Supreme Court, U.S.
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No.

In the Supreme Court of the United States

CITIZENS FOR HEALTH; AMERICAN ASSOCIATION FOR HEALTH FREEDOM; AMERICAN ASSOCIATION OF PRACTICING PSYCHIATRISTS; AMERICAN MENTAL HEALTH ALLIANCE-USA; AMERICAN PSYCHOANALYTIC ASSOCIATION; NATIONAL COALITION OF MENTAL HEALTH PROFESSIONALS AND CONSUMERS; NEW HAMPSHIRE CITIZENS FOR HEALTH FREEDOM; SALLY SCOFIELD; TED KOREN, DC; MICHAELE DUNLAP, PSY.D.; MORTON ZIVAN, PH.D.; CALIFORNIA CONSUMER HEALTHCARE COUNCIL; CONGRESS OF CALIFORNIA SENIORS; HEALTH ADMINISTRATION RESPONSIBILITY PROJECT; DANIEL S. SHRAGER; EUGENE B. MEYER; JANE DOE; JANIS CHESTER; DEBORAH PEEL,
PETITIONERS

v.

* MICHAEL O. LEAVITT, SECRETARY U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR WRIT OF CERTIORARI

JAMES C. PYLES
Counsel of Record
Powers, Pyles, Sutter & Verville, P.C.
1875 Eye St., N.W.
Washington, D. C. 20006
202-466-6550

CURRY & TAYLOR ♦ WASH D.C. ♦ (202) 223-3160 ♦ USSCINFO.COM

QUESTIONS PRESENTED

I. Whether the Court of Appeals decision conflicts with relevant decisions of this Court by holding that state action for a constitutional challenge to the deprivation of a right to liberty cannot exist unless the law in question "suddenly authorized something that was previously prohibited".

II. Whether the Court of Appeals decision conflicts with relevant decisions of this Court by holding that state action may exist only where the State has "compelled" a particular act or "commanded" a particular result.

III. Whether the Court of Appeals decision conflicts with relevant decisions of this Court and decisions of other United States Courts of Appeals by failing to consider other relevant state action criteria.

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The opinion of the Court of Appeals, Citizens for Health, et al. v. Leavitt, 428 F.3d 167 (3rd Cir. 2005), the order denying rehearing and rehearing en banc, and the opinion of the District Court, Citizens for Health, et al. v. Thompson, 2004 WL 765356 (E.D. Pa. 2004) are attached at App. 1a-83a.

JURISDICTION

The judgment for which Plaintiffs seek review was entered on October 31, 2005. Plaintiffs' Petition for Rehearing and Rehearing En Banc was denied on January 13, 2006. This Court has jurisdiction to review this matter on a writ of certiorari under 28 U.S.C. 1254.

RELEVANT PROVISIONS INVOLVED

First, Fourth, Fifth and Ninth Amendments to the U.S. Constitution

Health Insurance Portability and Accountability Act of 1996 (HIPAA)
Pub. L. 104-191, 110 Stat. 1936, Title II, Subtitle F, §264(c)

Standards for Privacy of Individually Identifiable Health Information

45 C.F.R. §164.506(a), 65 Fed. Reg. 82,810 (Dec. 28, 2000)
(Original Rule)

45 C.F.R. §164.506(a), 67 Fed. Reg. at 53,268 (Aug. 14, 2002)
(Amended Rule)

(See Appendix)

STATEMENT

Plaintiffs in this case ("Citizens") are nine individuals and ten national and state associations representing approximately 750,000 consumers, medical practitioners and their patients whose health information privacy began to be violated prospectively and retroactively on April 14, 2003 by "covered entities", which include the Secretary and private organizations, using an Amended Health Information Privacy Rule ("Amended Rule") issued by the Secretary of Health and Human Services ("HHS"). 67 Fed. Reg. 53,182 (Aug. 14, 2002). The Amended Rule, for the first time in the nation's history, conferred federal authority on federal officials and private entities to routinely use and disclose virtually all identifiable health information about any individual without consent and over the individual's objection. The Rule thereby transferred the locus of decision-making regarding disclosures from Citizens to covered entities and their business associates.

Because the Secretary did not submit any evidence contesting Citizens' allegations, the facts are not in dispute. Citizens' comprehensive complaint was verified in detail by 25 affidavits and hundreds of notices of privacy practices issued on or after April 14, 2003 showing that Citizens' identifiable health information was being, or was about to be, disclosed by covered entities without notice, without their consent, and over their objections relying on the "regulatory permission", authority, encouragement and support provided by the Amended Rule.

The Secretary in a predecessor Administration, issued the Original Privacy Rule on December 28, 2000 to implement section 264 of HIPAA which required the issuance of regulations setting forth the health information privacy rights individuals "should have" as part of new standards to facilitate the electronic transmission and storage

of health information. 65 Fed. Reg. 82,462. Upon assuming office, the current Administration delayed the Original Rule's effective date and reopened the comment period from February 28 through March 30, 2001. 66 Fed. Reg. 12,434, 12,738. After an expedited review of additional comments, the Secretary put the Original Rule into effect on April 14, 2001 with a two year delayed implementation date (April 14, 2003), as required by the statute. Id.

The Original Rule recognized a right to health information privacy and consent with respect to the use and disclosure of identifiable health information by "covered entities" and their "business associates" for "routine" uses defined as "treatment, payment and health care operations". [1] HHS found that Congress had recognized strong privacy protections "are a *sine qua non* of the increased efficiency...brought about by the electronic revolution." 65 Fed. Reg. at 82,474. Strong privacy measures were deemed essential because (a) there is growing public concern about the loss of personal privacy in electronic information systems, (b) the increasing use of "interconnected" electronic information systems renders health privacy more vulnerable, (c) highly sensitive health information, such as genetic information, is becoming more available, and (d) increased numbers of people have access to others' health information. 65 Fed. Reg. at 82,465-66.

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[1] Covered entities are defined as health plans, health care clearinghouses or health care providers; business associates means anyone who handles health information on behalf of covered entities including bill collectors, consultants, accountants, lawyers, and data aggregators . 45 C.F.R. §160.102. According to HHS, there are over 600,000 covered entities and millions of business associates. 66 Fed. Reg. at 12,739. Health plans include federally administered health programs such as Medicare, Medicaid, and the Indian Health Service. 45 C.F.R. §160.103. Treatment, payment and health care operations are approximately 80 broad uses and disclosures including premium rating, business planning and development, management services and due diligence in the potential sale of a business. 45 C.F.R. §164.501

The preamble to the Original Rule recognized that the right to privacy is essentially "the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated". 65 Fed. Reg. at 82,465. It also concluded that "[p]rivacy is a fundamental right" traditionally protected by state statutory and common law, federal constitutional law, and the law of psychotherapist-patient privilege. 65 Fed. Reg. at 82,464. HHS also found that privacy is essential for effective, high quality health care. 65 Fed. Reg. at 82,467.

Finally, HHS determined that the right of consent, as the means of exercising the right to privacy, was part of traditional standards of medical practice as evidenced by standards of medical ethics, most state laws, and the prevailing practice in the country. 65 Fed. Reg. at 82,472-74, 82,771. The right of consent was deemed essential to the right to privacy as evidenced by comments from consumers and most health care practitioners. 65 Fed. Reg. at 82,473. Thus, the Original Rule recognized the right of consent for routine disclosures. 45 C.F.R. §164.506(a), 65 Fed. Reg. at 82,810.

On March 27, 2002, the Secretary proposed reversing his prior decision and eliminating the individual's right of consent for the use and disclosure of identifiable health information for routine purposes. 67 Fed. Reg. 14,776. Despite receiving comments from individuals and organizations representing over 100 million consumers and practitioners objecting to elimination of the right of consent, the Secretary issued the Amended Rule on August 14, 2002 that not only eliminated the individual's right of consent, but also granted "regulatory permission" to all covered entities to use and disclose Citizens' health formation for the eighty "routine" uses without notice, without consent and even over their objection. 67 Fed. Reg. at 53,211, 45 C.F.R. §164.506(a), 67 Fed. Reg. at 53,268. The Secretary did not

address HHS' prior findings with respect to health privacy being a fundamental constitutional right. This reversal of policy effectively converted the Original "Privacy" Rule into a "disclosure" rule, because the broad definitions of "routine" uses now worked to broadly eliminate rather than preserve the right to privacy. That authority was conferred on all covered entities including the Secretary as administrator of the Medicare, Medicaid and Indian Health Services programs.

Citizens filed this action in District Court for the Eastern District of Pennsylvania on April 10, 2003, four days before the April 14, 2003 implementation date of the Amended Rule, seeking an injunction of the Amended Rule's elimination of the right of consent and the authorized nonconsensual disclosures of Citizens' identifiable health information. A First Amended Complaint was filed on May 5, 2003. Citizens challenged the Amended Rule on the grounds that (a) it violated Citizens' right to informational privacy protected by the Fourth, Fifth and Ninth Amendments to the Constitution and the right to private communications with medical practitioners protected by the First Amendment , (b) it violated the psychotherapist-patient privilege recognized by this Court [2], (c) it was not authorized by section 264 of HIPAA and (d) the Secretary's reversal of position was "arbitrary and capricious" action prohibited by the Administrative Procedure Act. First Amended Complaint at paras. 65-83.

The parties cross-moved for summary judgment, and the District Court issued a decision on April 2, 2004 ruling in Citizens favor on standing but granting the Secretary's motion based on the following findings:

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[2] Jaffee v. Redmond, 518 U.S. 1, 116 S. Ct. 1923 (1996).

(1) Citizens had standing to raise the claims because they showed that: (a) their identifiable health information already had been or would be disclosed without their consent on and after April 14, 2003 by covered entities relying expressly on the "regulatory permission" granted them by the Amended Rule, (b) the Amended Rule "changed the landscape" with respect to whether consent is required for disclosure of identifiable health information, (c) Citizens could not protect their right to privacy and consent even by withholding health information because information already in their records could be disclosed without their consent under the authority of the Rule, (d) Citizens are limiting the health information they disclose and are even avoiding seeking health care altogether for themselves and their families because of the privacy violations authorized by the Rule, (e) the right under the Amended Rule for Citizens to request a consent process is rendered meaningless by the fact that the Rule permits all such requests to be summarily denied and such requests, in fact, have been uniformly denied and (f) it is likely, as opposed to speculative, that enjoining the Amended Rule will redress the injuries caused to Citizens' privacy by the Rule. App. 59a-65a.[3]

(2) The Court refused to consider Citizens' constitutional claims and even refused to acknowledge that there is a constitutionally protected right to information privacy because the Court erroneously believed Citizens were asserting that the Secretary had a constitutional duty to protect them from health privacy intrusions by affording a consent process. See decision at App. 75a, relying on DeShaney v. Winnebago Co. Soc. Servs. Dep't, 489 U.S. 189, 195, 109 S. Ct. 998 (1989).[4]

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[3] The District Court had jurisdiction under 28 U.S.C. Sec. 1331.

[4] The court did not dispute that constitutional protection for the right to health information privacy has been recognized in Ferguson v. City of

(3) The Court concluded that the Amended Rule was reasonably related to the legislative purposes of the statute and that it was not retroactive because it did not impair stricter privacy rights created by state law, ethics codes or standards of practice. App. 71a-74a.

(4) The Court also rejected Citizens' Administrative Procedure Act challenge concluding that the Secretary provided a reasoned analysis for reversing the decision to recognize a right to privacy and consent despite the fact that the he ignored the findings on which that decision was based and relied on the same evidence for the policy reversal. App. 65a-71a.

Citizens sought de novo review by the Court of Appeals on the same issues. After oral argument on March 9, 2005, the Court of Appeals requested the parties to address additional written questions with respect to whether there was a justiciable case or controversy, whether the correct defendant was before the court and, if so, whether additional testimony before the district court might be necessary and the appropriate remedy if the Amended Rule were invalidated. The state action issue was not raised by the Court or either party nor did the Court request the issue be addressed in post-hearing briefing. [5]

Charleston, 532 U.S. 67, 121 S. Ct. 1281 (2001); and Whalen v. Roe, 429 U.S. 589, 97 S. Ct. 869 (1977).

[5] Six amicus curiae briefs were filed in support of Citizens' constitutional challenge by the Program for Psychiatry and the Law at Harvard Medical School, the Association of American Physicians and Surgeons, past presidents of the Massachusetts Medical Society and past chair of the American Medical Association Council on Ethics and Judicial Affairs, the National Association of Social Workers, NARAL Pro-Choice America Federation, Consumer Attorneys of California and the Texas Civil Rights Project. Only the Texas Civil Rights Project addressed the state action issue.

On October 31, 2005, the Court of Appeals issued a decision affirming the District Court's decision, although on different grounds with the following holdings:

(1) All of the issues with respect to standing, justiciability, proper defendant, need for additional testimony, and appropriate remedy were decided in Citizens' favor. App. 11a.

(2) Citizens had standing to bring this suit because (a) they demonstrated through affidavits and other evidence that their identifiable health information had been, or imminently would be, disclosed without consent by covered entities and that they and their families were avoiding seeking health care to prevent further non-consensual disclosures, (b) prior to April 14, 2003, Citizens had the ability to prevent non-consensual disclosures of their identifiable health information, (c) notices of privacy practices from covered entities beginning April 14, 2003 showed an intent to use and disclose Citizens' health information without consent using language taken directly from the Amended Rule, and (d) Citizens showed that they, in fact, had lost the ability to prevent such disclosures on the Amended Rule's implementation date. App. 34a.

(3) The Court agreed with Citizens that the DeShaney decision was not dispositive of the constitutional claims because they were not seeking protection by the Secretary of their right to privacy but, rather, were seeking protection from the Court for their constitutional right to privacy with respect to actual or threatened violations by covered entities, including the Secretary, exercising federal authority. App. 12a.

(4) The Court of Appeals, however, refused to address Citizens' constitutional claims, this time based on the holding that there was no state action since the Amended Rule allegedly did not "compel" or "command" the privacy violations and on the unprecedented proposition that state action could not be present unless the Amended Rule suddenly authorized something that was previously prohibited. App. 17a-18a, 25a.

(5) The Court of Appeals summarily affirmed the District Court with respect to Citizens' statutory and Administrative Procedure Act claims. App. 25a-29a.

Citizens filed a timely petition for rehearing and rehearing en banc on the grounds that the Court of Appeals had failed to obtain briefing on the state action issue and had ignored controlling Third Circuit and Supreme Court precedent interpreting the state action doctrine. That petition was denied, without opinion, on January 13, 2006.

REASONS FOR GRANTING THE PETITION

I. The Court of Appeals' holding that state action cannot exist unless the state "suddenly authorized something that was previously prohibited" conflicts with relevant decisions of this Court.

According to the Court of Appeals, state action can not exist, "unless the law itself suddenly authorized something that was previously prohibited." App. 18a. The Court further stated that state action is not present where the government "only codifies" a power that private parties had already. App. 19a. To illustrate its point, the Court stated that legislation passed by Congress

would be insulated from constitutional challenge if it were to permit private cinema operators, at their discretion, to search all movie goers for any reason. Id. Under this formulation of the state action doctrine, Congress (or a federal agency or a state) could insulate any action or policy from Constitutional challenge if it could point to an example of a similar action or policy in the private sector. By holding that the state may immunize its actions from constitutional scrutiny based on private violations of individual liberties, the Court has turned the state action doctrine into a legal nullity.

The Court cited no case law to support its novel proposition, and Citizens is aware of none. Citizens believe this is because the proposition is contrary to the basic principles of the state action doctrine recognized in numerous decisions of this Court. As the Court of Appeals acknowledged, the "state action" doctrine developed in the civil rights cases decided over more than 100 years following the Civil War. App. 16a-17a. "The Civil Rights Cases", 109 U.S. 3, 3 S. Ct. 18 (1883); Shelley v. Kraemer, 334 U.S. 1, 68 S. Ct. 836 (1948); Garner v. State of Louisiana, 368 U.S. 157, 82 S. Ct. 248 (1961); Peterson v. City of Greenville, 373 U.S. 244, 83 S. Ct. 1119 (1963); Lombard v. State of Louisiana, 373 U.S. 267, 83 S. Ct. 1122 (1963); Robinson v. Florida, 378 U.S. 153, 84 S. Ct. 1693 (1964); Reitman v. Mulkey, 387 U.S. 369, 87 S. Ct. 1627 (1967); Adickes v. S. H. Kress, 398 U.S. 144, 90 S. Ct. 1598 (1970); Moose Lodge No. 107 v. Irvis, 407 U.S. 163, 92 S. Ct. 1965 (1972); Norwood v. Harrison, 413 U.S. 455, 466, 93 S. Ct. 2804, 2811 (1973); Gilmore v. City of Montgomery, 417 U.S. 556, 94 S. Ct. 2416 (1974).

These decisions establish that state action exists where the State requires, adopts, approves, encourages, enforces or in some way supports racial discrimination

which has long been conducted by private entities. State action was found in these cases where the law in question authorized or enforced an action or a policy that was previously permitted, rather than prohibited, among private individuals and entities.

In announcing the state action doctrine in "The Civil Rights Cases", this Court stated that the Constitution "nullifies and makes void ...state action **of every kind** which impairs the privileges and immunities of citizens of the United States, or which injures them in life, liberty, or property without due process of law...". 109 U.S. at 11, 3 S. Ct. at 21 (emphasis added). Included within the scope of state action are "the wrongful acts of individuals, [ ]supported by state authority in the shape of laws, customs, or judicial or executive proceedings." 109 U.S. at 17, 3 S. Ct. at 25. Accordingly, protection under the state action doctrine extends to the deprivation of any Constitutionally guaranteed right, like medical privacy, where that deprivation is supported by state action.

In fact, this Court noted that the private actions that were the subject of the complaint ("denying to individuals the privileges and accommodations of a theater" and other types of discrimination) would be prohibited if they were supported by state action, even though those deprivations had been common practice in the private sector throughout the history of the United States. 109 U.S. at 22-23, 3 S. Ct. at 29. Subsequent cases applied these principles.

For example, state action supporting the prior private practice of racial discrimination was found in (a) the action of state courts upholding restrictive covenants in land sales contracts, Shelley v. Kraemer, 334 U.S. 5-6, 68 S. Ct. 838-9; (b) a trespass statute used to enforce a city ordinance supporting a "local custom" of restaurant

owners to discriminate against minorities, Peterson v. City of Greenville, 373 U.S. 246, 83 S. Ct. 1120; (c) statements of city officials supporting the common practice of restaurants refusing to permit segregated dining, Lombard v. Louisiana, 373 U.S. 272, 83 S. Ct. 1125; (d) state regulations discouraging restaurants from departing from past practices of refusing to serve minorities, Robinson v. Florida, 378 U.S. 156, 84 S. Ct. 1695; (e) state application of a "disturbance of the peace" statute to enforce a private restaurant's segregation policy, Garner v. Louisiana, 368 U.S. 160, 173, 82 S. Ct. 249, 256; (f) a State constitutional amendment that authorized existing racial discrimination in the housing market, Reitman v. Mulkey, 387 U.S. 373, 381, 87 S. Ct. 1630, 1634; (g) a trespass law which was applied to enforce "a long-standing and still prevailing" custom of operating racially segregated restaurants, Adickes v. S.H. Kress, 398 U.S. 173, 90 S. Ct. 1616; (h) a state regulation requiring a private club to adhere to its bylaws supporting its practice of discriminating against minorities in the provision of services, Moose Lodge No. 107 v. Irvis, 407 U.S. 178, 92 S. Ct. 1974; (i) a statute that provided books to private schools operating on a segregated basis, Norwood v. Harrison, 413 U.S. 466, 93 S. Ct. 2811; and (j) a city policy of allocating facilities for use by private segregated schools in order to perpetuate existing private discrimination, Gilmore v. City of Montgomery, 417 U.S. 566-67, 94 S. Ct. 2423.

Under the Court of Appeals' interpretation of the state action doctrine, racial discrimination invalidated in these cases could still be the norm. Using the Court's example, a law passed by Congress authorizing cinema operators to deny access to minorities would be immune to constitutional challenge. Clearly such a law would constitute state action under the holdings in the above cases. State action typically is found where the state puts

its weight on the side of the proposed practice so that private individuals "need no longer rely on their personal choice" but can invoke express state authority to support their previously private conduct. Jackson v. Metro. Edison Co., 419 U.S. 345, 357, 95 S. Ct. 449, 456 (1974); Reitman v. Mulkey, 387 U.S. 377, 87 S. Ct. 1632.

That has clearly occurred here where, after the implementation of the Amended Rule, covered entities, including the Secretary, no longer needed to rely on their personal choice but could, and did, disclose Citizens' identifiable health information relying on "regulatory permission" granted by the Rule. The evidence shows that nearly all providers obtained consent to disclose Citizens' health information prior to implementation of the Amended Rule. App. 35a and 23a, 65 Fed. Reg. at 82,472, 82,771. Even if covered entities theoretically could have disclosed Citizens' health information without federal authority, that possibility alone does not preclude a finding of state action where the Secretary has created a regulatory scheme that encourages and enforces private policies of nonconsensual disclosures. Reitman v. Mulkey, 387 U.S. 379-80, 87 S. Ct. 1633.

II. The Court of Appeals' holding that state action may exist only where the state has "compelled" a particular act or "commanded" a particular result conflicts with relevant decisions of this Court.

The Court of Appeals concluded that state action may exist only where the state, by its law "has compelled the act" or when the state has "'commanded' a particular result." See App. 17a., relying on Adickes v. S.H. Kress & Co., Peterson v. City of Greenville, Robinson v. Florida, Lombard v. Louisiana, and Shuttlesworth v. Birmingham , 373 U.S. 262,

83 S. Ct. 1130 (1963). That conclusion is in conflict with the holdings in these and other decisions of this Court.

The Court in Adickes did not specify the state action that actually existed because the case was remanded without such a ruling due to the lower court's premature award of summary judgment. 398 U.S. at 160-61, 171, 90 S. Ct. at 1609-10, 1615-17. The Court, however, described a broad range of evidence that could support a state action finding.

The case involved a Caucasian school teacher who was refused service when she sought to dine with several African-American students at a restaurant and was arrested for vagrancy after she left. 398 U.S. at 146, 90 S. Ct. at 1602. The statute under which she was arrested did not compel or otherwise command segregation, she was not asked to leave the restaurant, and she was not arrested for being on the premises. 398 U.S. at 161, n. 23, 90 S. Ct. at 1610.

The plaintiff could show abridgement of her constitutional rights, according to the Court, if she could prove that the restaurant refused her service because of "a state-enforced custom of segregating the races in public restaurants" having the force of law. 398 U.S. at 171, 90 S. Ct. at 1615. This concept of state action recognizes that "settled practices of state officials may, by imposing sanctions or withholding benefits, transform private predilections into compulsory rules of behavior." 398 U.S. at 168, 90 S. Ct. at 1614. In other words, state action can be found in the influence on private decisions by state enforcement or discouragement of those decisions.

The Court of Appeals noted that the Adickes Court used "two polar propositions" to analyze the state action issue—one where the state itself is discriminating because of race and the other where a private party is acting on his own personal predilections and "not...against a backdrop of state

compulsion or involvement." 398 U.S. at 169, 90 S. Ct. at 1614-15 (emphasis added.) App. 16a. The Court of Appeals, however, focused exclusively on the "compulsion" branch of the Adickes analysis and ignored the broader "involvement" branch. [6] The Adickes Court also stated that it was not deciding "whether less substantial involvement of a State might satisfy the state action requirement." 398 U.S. at 171, 90 S. Ct. at 1615. Such less substantial involvement was identified in the following other decisions.

The Court in Peterson v. City of Greenville, 373 U.S. 244, 248, 83 S. Ct. 1119, 1121 (1963) found state action in the application of a non-discriminatory trespass statute because it was used to enforce a city ordinance expressly

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[6] The Court also misstated Citizens' allegations, effectively avoiding the fact that the other "pole proposition"--direct state involvement-- is also present in this case. The Court conceded that Citizens and Amici had referred to the Secretary's grant of "regulatory permission" to himself to violate Citizens' privacy rights in his role as a "covered entity" charged with administration of the Medicare, Medicaid and Indian Health Services programs. App. 14a, n.12, 38a. The Court concluded it did not have to decide whether this grant of direct authority constituted state action because Citizens challenged the promulgation of the rule, "not specific disclosures by HHS." Id. The Court supported this conclusion by stating that Citizens had alleged only that their privacy was being violated by "third parties". App. 14a, citing Citizens' Br. at 2. In fact, the allegation to which the Court referred stated that Citizens' health information privacy was being violated by "covered entities exercising federal authority granted by the Amended Rule." Citizens' Br. at 2. Further, Citizens expressly alleged in their complaint that the Secretary had violated their rights to privacy by eliminating their right of consent and expressly authorizing "all covered entities and their business associates" to disclose Citizens' health information without their permission and against their will. First Amended Complaint, para. 71. The Secretary is indisputably a covered entity. Also, one of the Plaintiffs is the Congress of California Seniors comprised of individuals insured principally under the Medicare and Medicaid programs administered by the Secretary. First Am. Comp., para. 20. Thus, the Court should have considered whether the Secretary's direct violation of Citizens' health privacy resulted in state action but failed to do so.

requiring discrimination in restaurants. Id. The principle on which the decision rests is that state action is present when "to some significant extent the State in any of its manifestations has been found to have become involved" in abridging individual rights. 373 U.S. at 247.

The Court in Lombard v. State of Louisiana, 373 U.S. 267, 269, n. 1, 83 S. Ct. 1122, 1123 (1963) expanded this principle. Several Caucasian and African-American individuals who staged a "sit-in" demonstration at a refreshment counter were arrested under a state trespass statute. State action was found in the form of non-binding public statements by the Superintendent of Police and the Mayor that "sit-ins" would not be tolerated. 373 U.S. at 273, 83 S. Ct. at 1125. Neither the state statute nor the officials' statements compelled or commanded proprietors to discriminate. They were entirely free to integrate their facilities without violating any state law. 373 U.S. at 270-271, 83 S. Ct. at 1123-24. The decision in Lombard stands for the proposition that "an authoritative expression of state policy that is nondiscriminatory on its face may be found to be discriminatory when considered against the factual background of its promulgation (citations omitted)." Adickes v. Kress, 398 U.S. at 193, 90 S. Ct. at 1621, Brennan, J., concurring in part and dissenting in part (emphasis added).

The state action doctrine was developed further in Robinson v. Florida, 378 U.S. 153, 154, n. 1, 84 S. Ct. 1693, 1694 (1964). That case involved prosecution of a mixed race group of individuals under a state trespass statute when they refused to leave a restaurant that had a "policy" of refusing to serve African-Americans. The statute gave the restaurant complete discretion to deny services to anyone who would be "detrimental" to serve. The State had a regulation and an administrative policy requiring restaurants that elected to serve African-Americans to have separate "facilities", such as toilet facilities. Neither the statute nor the regulation and

administrative policy "compelled" or "commanded" the policy adopted by the restaurant. The Court found state action to support a constitutional challenge with the following rationale:

> While these Florida regulations do not directly and expressly forbid restaurants to serve white and colored people together, they certainly embody a state policy putting burdens upon any restaurant which serves both races, burdens bound to discourage the serving of the races together.

378 U.S. at 156, 84 S. Ct. at 1695. Thus, the state was found to be involved to a "significant extent" due to a state policy that simply imposed burdens discouraging integration.

The Peterson, Lombard, and Robinson "sit-in" cases do not stand for the proposition that state action can be present only where private action is "compelled" or "commanded", but rather that state action is present where there is significant state involvement in the form of supporting, encouraging, discouraging or enforcing private decisions.[7]

That conclusion was noted three years after Robinson in Reitman v. Mulkey, 387 U.S. 369, 376, 87 S. Ct. 1627, 1631 (1967), where the Court stated that "prohibited state involvement could be found 'even where the state can be charged with only encouraging' rather than commanding discrimination" citing, Robinson; Anderson v. Martin, 375 U.S. 399, 84 S. Ct. 454 (1964); Barrows v. Jackson, 346 U.S. 249, 73 S. Ct. 1031 (1953); McCabe v. Atchison, Topeka &

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[7] In Shuttlesworth, convictions for aiding and abetting violation of a city trespass ordinance were dismissed for lack of evidence, but the ordinance did not compel or command discrimination. 373 U.S. at 263, n. 2, 83 S. Ct. at 1131.

Santa Fe R. Co., 235 U.S. 151, 35 S. Ct. 69 (1914).[8] In Reitman, an amendment to the state constitution guaranteed the right to sell or lease real property to anyone that an individual, "in his absolute discretion, chooses." 387 U.S. at 372, n. 2, 87 S. Ct. at 1629. Accordingly, the action by private property owners refusing to rent to minorities was not compelled or commanded by the amendment. State action nonetheless was found to hold the state provision unconstitutional because it was "intended to authorize, and does authorize, racial discrimination in the housing market." 387 U.S. at 381, 87 S. Ct. at 1634. So, Reitman stands for the proposition that private conduct need not be "compelled" or "commanded" in order for state action to be found but may be only encouraged, authorized or supported as evidenced by the intent, effect, and historical context of the contested action. 387 U.S. at 373, 87 S. Ct. at 1630.[9]

This Court applied these principles again in Moose Lodge No. 107 v. Irvis, 407 U.S. 163, 176, 92 S. Ct. 1965, 1973 (1972), where it found a private club's policy of refusing to serve African-Americans was constitutionally

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[8] The Reitman Court also noted that that state action had been found in Burton v. Wilmington Parking Authority, 365 U.S. 715, 81 S. Ct. 856 (1961) even though the State "neither commanded nor expressly authorized or encouraged the discrimination" but only "elected to place its power, property and prestige behind the admitted discrimination". 387 U.S. at 380, 87 S. Ct. at 1633.

[9] Indeed, this Court's landmark decision in Brown v. Board of Education, 374 U.S. 483, 486 n. 1, 74 S. Ct. 686, 687 (1954) which spawned many of the cases that refined the state action doctrine, involved a Kansas statute "which permits, but does not require" cities of a certain size to maintain separate school facilities for Caucasian and African-American students. That statute was struck down as unconstitutional along with others that required separate facilities. This Court has often found laws that permit but do not require certain private acts to be in violation of constitutional rights. Santa Fe Indep. School Dist. v. Doe, 530 U.S. 290, 309, 120 S. Ct. 2266, 2282 (2000); Wallace v. Jaffree, 472 U.S. 38, 40, 105 S. Ct. 2479, 2481, 2491 (1985).

defective based on state action in the form of a state regulation that simply required private clubs to comply with their own bylaws. There was "no suggestion" that the state regulation required private clubs to discriminate or that it had been applied to that effect. The state action resulted solely from the potential "application" of the rule. 407 U.S. at 178, 92 S. Ct. at 1974.

State action was also found in Norwood v. Harrison , 413 U.S. 455, 93 S. Ct. 2804 (1973) in a state statute that provided books for both public and private schools without regard to whether the private schools had racially discriminatory policies. According to that decision, state action can be any tangible aid that "has a significant tendency to facilitate, reinforce, and support private discrimination". 413 U.S. at 466, 93 S. Ct. at 2811. The constitutionally defective statute did not compel or command private segregation, and the private schools were not coerced in any way to adopt discriminatory policies. The Court further held that the state is prohibited by the Constitution from engaging directly in discriminatory conduct, and "'[i]t is axiomatic that a state may not induce, encourage or promote private persons to accomplish what it is constitutionally forbidden to accomplish." 413 U.S. at 465, 93 S. Ct. at 2810.

A similar holding was reached in Gilmore v. City of Montgomery, 417 U.S. 556, 94 S. Ct. 2416 (1974). There this Court found state action in a city policy that allocated facilities to private schools that were racially segregated. The city's policy did not compel or command segregation, and the schools had complete discretion to operate on a segregated or desegregated basis. State action was found because the city's policy "enhanced the attractiveness of segregated private schools" enabling them to offer complete athletic programs. According to the Court, this resulted in "significant state involvement" in private discrimination. 417 U.S. at 573, 94 S. Ct. at 2426.

In both Edmonson v. Leesville Concrete Co., 500 U.S. 614, 111 S. Ct. 2077 (1991) and Georgia v. McCollum, 505 U.S. 42, 112 S. Ct. 2348 (1992), this Court struck down the racially motivated exercise of peremptory challenges by private individuals in civil (Edmonson) and criminal (McCollum) court proceedings even though the actions were authorized by facially neutral statutes. The individuals in these cases were not compelled, or even encouraged, to exercise their statutory rights in a racially discriminatory manner. The Court in both cases found that the trial court's enforcement of the racially motivated private decisions involved the government "in a significant way" in otherwise private discrimination. 500 U.S. 624, 111 S. Ct. 2085; 505 U.S. 55, 112 S. Ct. 2356-57.

Finally, this Court has applied the state action principles developed in the civil rights area in other contexts. In Skinner v. Railway Labor Executives, 489 U.S. 602, 109 S. Ct. 1402 (1989), the Court struck down on constitutional grounds a federal regulation that was entirely permissive in that it merely authorized railroads to require employees to submit to breath and urine tests in certain circumstances. Nothing in the regulation compelled any such testing by the railroads. 489 U.S. at 602, 611, 614, 109 S. Ct. at 1407, 1410, 1411. Addressing the state action issue, the Court stated, "[t]he fact that the Government has not compelled a private party to perform a search does not, by itself, establish that the search is a private one." 489 U.S. at 615, 109 S. Ct. at 1412. According to the Court, state action is present where the government "has done more than adopt a passive position" toward the particular private decision, but rather, has shown a "strong preference" for the conduct and there are "clear indices of the Government's encouragement, endorsement and participation." Id.

The facts in Skinner, involving government permission and encouragement of private entities to conduct random searches, are analogous to the random searches example used by the Court of Appeals to illustrate its novel state action concept. App. 19a. The rationale of Skinner, grounded in more than 100 years of Supreme Court case law, shows that state action is present where the federal government merely authorizes, encourages or endorses but does not compel or command, searches of private citizens by private entities. Thus, the Court's own example plainly shows that its holding is in conflict with decisions of this Court.

III. The Court of Appeals' decision conflicts with relevant decisions of this Court and decisions of other Courts of Appeal by failing to address relevant state action criteria.

This Court recently set forth the analysis that courts must apply in determining whether state action is present in a case with a constitutional claim. According to the Court, "the judicial obligation is not only to 'preserv[e] an area of individual freedom by limiting the reach of federal law' and avoi[d] the imposition of responsibility on a State for conduct it could not control,' [citations omitted] but also to assure that constitutional standards are invoked 'when it can be said that the State is *responsible* for the specific conduct of which the plaintiff complains'". Brentwood Academy v. Tennessee Secondary School Ass'n, 531 U.S. 288, 295, 121 S. Ct. 924, 930, (2001) (emphasis added). According to the Court, "if the [Constitution] is not to be displaced, therefore, its ambit cannot be a simple line between States and people operating outside formally governmental organizations, and the deed of an ostensibly private organization or individual is to be treated sometimes as if the State had caused it to be performed." (emphasis added) Id. The question is whether there is such a "close nexus" between the state and the

challenged action that "seemingly private behavior 'may be fairly treated as that of the State itself'". Id., citing Jackson v. Metro. Edison Co. 419 U.S. 345, 351, 95 S. Ct. 449 (1974).

Action that is fairly attributable to the state under Brentwood, "is a matter of normative judgment, and the criteria lack rigid specificity ...no one fact can function as a necessary condition across the board for finding state action; nor is any set of circumstances absolutely sufficient...". The Court noted that "[o]ur cases have identified a host of facts that can bear on the fairness of such an attribution." 531 U.S. at 296, 121 S. Ct. at 930. Criteria cited by the Court for determining the presence of state action include where the action results from the state's exercise of "coercive power", "when the State provides 'significant encouragement, either overt or covert", "when a private actor operates as a 'willful participant in a joint activity with the State or its agents'", "when it is 'entwined with the government policies' or when government is 'entwined in [its] management or control'"(citations omitted). Id. The Court must perform a "necessarily fact-bound inquiry". Id. at 298. The mere fact that state action may not be present under one set of criteria does not mean that it should not be found under others. Id. at 302.

The Court of Appeals completely ignored Brentwood despite the fact that Citizens cited the decision and the state action criteria it mandates in its post-hearing memorandum. Appellants' Memorandum in Response to Questions from the Court, pp. 10-11 (April 8, 2005). Instead, the Court of Appeals addressed only a single state action criterion—whether the private action was "compelled" or "commanded" by the Secretary's regulation. App. 17a. Thus, the Court of Appeals failed to discharge its "judicial obligation" to assure that "constitutional standards are invoked" where, as here, Citizens' fundamental liberty rights have been, or imminently will be, violated by both the Secretary and by private entities

as expressly authorized, encouraged and enforced by the Amended Rule.

Brentwood reversed a finding of no state action by a Court of Appeals which had considered only three of the state action criteria established by this Court. 531 U.S. at 294. Review and reversal of the Court of Appeals' decision in this case is even more appropriate because that Court limited itself to the rigid application of only a single state action criterion to the exclusion of all others, and the Court affirmed the granting of summary judgment in favor of the government even though it had not disputed any of the facts alleged in the Verified Amended Complaint, affidavits and exhibits submitted by Citizens. At such a stage in a judicial proceeding, all such alleged facts must be taken as true and the inferences to be drawn from them must be viewed in the light most favorable to the party opposing such a motion. Adickes, supra at 158-161. See also, App. 34a, n. 9.

It is undisputed in this case that (a) the right to information privacy is the right to decide whether one's health information may be disclosed [10]; (b) the right to privacy is a fundamental right protected by the Constitution [11], (c) the Original Privacy Rule effective April 14, 2001 recognized this right to privacy and consent for identifiable health information further noting that a consent process is consistent with traditional practice and the public's expectation of privacy[12]; (c) the Amended Rule "replaced" the right of privacy and consent with "regulatory permission" for hundreds of thousands of covered entities (including the Secretary) to routinely use and disclose Citizens' identifiable health information without notice, without their consent and

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[10] 65 Fed. Reg. at 82,465

[11] 65 Fed. Reg. at 82,464.

[12] 45 CFR §164.506(a), 65 Fed. Reg. at 82,474, 82,771, 82,810 ——

over their objection[13]; (d) the Secretary's express intent in issuing this rule was to extinguish Citizens' right to privacy and consent in routine situations which the Secretary believed was an impediment to the efficient delivery of health care[14]; (e) the Amended Rule compels every covered entity to provide a notice of privacy practices which includes a description of the routine uses and disclosures that the entity is authorized by the Rule to make regardless of whether that is consistent with the entity's past, or current privacy practices[15]; and (f) beginning on the April 14, 2003 implementation date of the Amended Rule, virtually all covered entities switched from their past practice of obtaining consent for routine uses and disclosures to the nonconsensual use and disclosure of Citizens' health information as a result of the authority, encouragement, support and enforcement provided by the Amended Rule. [16]

Furthermore, the Court of Appeals determined, in ruling in Citizens' favor on standing, that covered entities are, or imminently will be, violating Citizens' health information privacy causing them "injury in fact" and that the injury is "causally connected and traceable" to the action of the Secretary. App. 34a, n. 9.

There is far more evidence of state authorization and encouragement in this case than was present in the non-binding oral statements in Lombard v. Louisiana, supra; the neutral state constitutional provision in Reitman v. Mulkey, supra; the "custom" of segregating races in Adickes v. S. H. Kress, supra; the state book supply statute in Norwood v. Harrison, supra; the city policy in Gilmore v. City of

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[13] 67 Fed. Reg. at 53,211, 45 CFR §164.506(a), 67 Fed. Reg. at 53,268

[14] 67 Fed. Reg. at 53,210-211.

[15] 45 CFR §164.520(b)(1)(ii)

[16] See, e.g., affidavits of Deborah Peel, M.D. as well as numerous other similar affidavits. J.A. 238-240, 312-314, 1476-1485 and generally, J.A. 46-332.

Montgomery, supra; the peremptory challenge statutes in Edmonson v. Leesville Concrete Co. supra and Georgia v. McCollum, supra; or the permissive federal drug testing regulation in Skinner v. Railway Labor Executives, supra. Yet the Court of Appeals in this case failed even to consider the overwhelming undisputed evidence under these criteria.

In addition to the significant encouragement to violate the Plaintiffs' health information privacy, the Amended Rule also provides significant discouragement to private entities that may wish to continue providing a consent process as they have in the past. The Amended Rule allows covered entities to provide a consent process only by means of a cumbersome process of granting an individual's request to depart from the privacy practices mandated by the Rule and entering into an agreement to restrict uses and disclosures.[17] Further discouragement is provided by the fact that failure of a covered entity to adhere to the agreement is a violation of the Rule subjecting the covered entity to potential civil sanctions.[18] The discouragement for covered entities to honor Citizens' right to privacy is clearly stronger than the discouragement reflected in the state regulations in Robinson v. Florida, supra for restaurants to serve races together. Yet the Court of Appeals did not consider this state action criterion.

As the Court of Appeals acknowledged, covered entities have adopted the disclosure practices mandated by the Amended Rule as their privacy practices as of the April 14, 2003 implementation date. App. 35a, n. 9, 23a. The Amended Rule compels these covered entities "to abide by the terms" of their stated privacy practices and enforces this requirement with civil penalties. 42 U.S.C. §1320d-5; 45

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[17] 67 Fed. Reg. at 53,213, 45 CFR §164.522.

[18] Id.

C.F.R. §160.402. [19] Thus, state action is present under the "enforcement" criterion of the state action doctrine. Moose Lodge No. 107 v. Irvis, supra, at 163. See also, Edmonson v. Leesville Concrete Co., supra at 624 and Georgia v. McCollum, supra, at 55. The Court of Appeals failed to consider this criterion as well.

This Court has also determined that state action may be found where the state has put its "imprimatur" or approval on the action. Blum v. Yaretsky, 457 U.S. 991, 1003, 102 S. Ct. 2777, 2785 (1982); Jackson v. Metro. Edison Co., supra at 357; Shelley v. Kraemer, supra at 20. That "imprimatur" is deemed to be present where the state has conducted a review of the proposed action and specifically approved it. Jackson, supra citing Public Utilities Comm'n v. Pollack, 343 U.S. 451, 72 S. Ct. 813 (1952). See also, Moose Lodge No. 107, supra at 176, n. 3 (state action exists where the government has "approved" or "endorsed" the violation). The undisputed evidence here is that the Secretary expressly approved and endorsed in the Amended Rule the unauthorized disclosures sought and proposed by certain covered entities. Further, the Court of Appeals found that covered entities are violating the health information privacy of Citizens "using language lifted directly from the Privacy Rule itself". App. 35a, n.9. The Court of Appeals found "regrettable and disquieting" the fact that covered entities are construing the authorization granted by the Amended Rule "as constituting a new federal seal of approval" to violate Citizens' health privacy. App. 23a. The Court, however, failed to consider whether this fact also amounts to state action.

State action also exists where the government has provided the "procedural scheme" and committed to enforce the deprivation of a constitutionally protected right. Lugar v.

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[19] 45 CFR §164.520(b)(1)(v)(B).

Edmonson Oil, 457 U.S. 922, 940, 102 S. Ct. 2744, 2756 (1982). The Court did not consider this criterion either.

Finally, this Court has repeatedly found that unconstitutional state action can be found in the intent and effect of a facially neutral law. Reitman v. Mulkey, supra at 381; Norwood v. Harrison, supra at 463-66 ; Gilmore v. City of Montgomery, supra at 568; Edmonson v. Leesville Concrete Co. supra at 624; Georgia v. McCollum, supra at 53. The stated intent and effect of the Amended Privacy Rule is to eliminate the ability of Citizens to exercise their rights to health information privacy in routine situations. The Court of Appeals did not consider whether this intent and effect could constitute state action.

The Court of Appeals decision also appears to be in conflict with the case law from at least two circuits holding that a variety of criteria must be considered in determining whether state action is present, and such state action can be evidenced by "encouragement and support" from the federal government even if it does not compel the private choice. For example, such encouragement and support sufficient for state action was present in a memorandum of understanding and the "structure of the program" where a spouse was deprived of access to his children under a federal witness protection program. Franz v. United States, 707 F.2d 582, 592-93 (D. C. Cir. 1983). See also, Breault v. Heckler, 763 F.2d 62, 64 (D.C. Cir. 1985) ("significant governmental promotion" sufficient for state action); Jeffries v. Georgia Residential Finance Authority, 678 F.2d 919, 923 (D. C. Cir. 1982), cert. denied 45 U.S. 971, 103 S. Ct. 302 (1982) (private citizen's conduct attributable to the state "where the government affirmatively facilitates, encourages, or authorizes the objectionable practice"). The law of the Fourth Circuit appears to be similar. Doe v. Charleston Area Medical Center, 529 F.2d 638, 643 (4th Cir. 1975) ("'government

sanction need not reach the level of compulsion to clothe what is otherwise private discrimination with 'state action'").

CONCLUSION

The Court of Appeals' decision in this case is based on a radical new formulation of the state action doctrine. The Court cited no precedent for its new state action theory, and the holding is in direct conflict with the holdings of this Court in the civil rights area which the Court of Appeals concedes formed the basis for the state action doctrine. The Court of Appeals' holding undermines virtually all constitutionally protected rights, and particularly civil rights, by insulating state action from constitutional scrutiny if the state can contend that it is merely codifying private violations of liberty.

The Court of Appeals' state action analysis is in direct conflict with the very cases on which it relies. Those cases, and their progeny, clearly show that private action need not be compelled or commanded in order for state action to be found. Under the Court of Appeals' example, Congress could enact a law, immune to constitutional challenge, authorizing cinema owners (or other private entities) to conduct random searches of individuals even if the law was expressly intended to encourage, promote, support and enforce such searches as a federal policy and the law was having its intended effect. In any event, the Court of Appeals erroneously ignored the fact that the actions determined to be actually or imminently causing Citizens' "injuries in fact" are being taken both by private entities as well as the Secretary expressly under the authority of the Amended Rule.

Finally, the Court of Appeals ignored the controlling precedent from this Court in Brentwood which defines the "judicial obligation" of courts evaluating the presence of state action to consider a "host of facts" and criterion that bear on

the fairness of attributing actions to the government. The Court of Appeals' holding that it may rigidly apply a single criteria and ignore all others directly conflicts with this Court's holding in Brentwood and will prevent constitutional standards from being invoked in many situations where the right to liberty is denied.

This case involves not only the question of whether individuals may raise any constitutional issue but also whether they may preserve their constitutional right to informational privacy. HHS found that the health information privacy rule "affects over 600,000 covered entities and virtually every American." 66 Fed. Reg. at 12,739. Citizens' identifiable health information which is being disclosed under the authority of the Amended Rule without their consent and over their objections includes their mental health and genetic information. If Citizens do not have a constitutionally protected right to privacy for their inner-most thoughts and genetic make-up, it is difficult to imagine how they could have any right to privacy. If there is no right to privacy, there can be no liberty. As often stated, "[t]he framers of the Constitution...conferred, as against the government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men." Olmstead v. United States, 277 U.S. 438, 478, 48 S. Ct. 564, 572 (1928) (Brandeis J., dissenting).

Accordingly, this case involves fundamental constitutional rights rooted in the nation's history and tradition and whether individuals will be able to exercise those rights. For these reasons, this petition should be granted.

Respectfully submitted,

James C. Pyles
Counsel of Record
Powers, Pyles, Sutter & Verville, P.C.
1875 Eye St., N.W.
Washington, D. C. 20006
202-466-6550

(any footnotes trail end of each document)

No. 04-2550

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

CITIZENS FOR HEALTH; AMERICAN ASSOCIATION FOR HEALTH FREEDOM; AMERICAN ASSOCIATION OF PRACTICING PSYCHIATRISTS; AMERICAN MENTAL HEALTH ALLIANCE-USA; AMERICAN PSYCHOANALYTIC ASSOCIATION; NATIONAL COALITION OF MENTAL HEALTH PROFESSIONALS AND CONSUMERS; NEW HAMPSHIRE CITIZENS FOR HEALTH FREEDOM; SALLY SCOFIELD; TED KOREN, DC; MICHAELE DUNLAP, PSY.D.; MORTON ZIVAN, PH.D.; CALIFORNIA CONSUMER HEALTHCARE COUNCIL; CONGRESS OF CALIFORNIA SENIORS; HEALTH ADMINISTRATION RESPONSIBILITY PROJECT; DANIEL S. SHRAGER; EUGENE B. MEYER; JANE DOE; JANIS CHESTER; DEBORAH PEEL,

Appellants,

v.

* MICHAEL O. LEAVITT, SECRETARY U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

March 9, 2005, Argued

October 31, 2005, Filed

COUNSEL: Robert N. Feltoon, Conrad, O'Brien, Gellman & Rohn, Philadelphia, PA; James C. Pyles [ARGUED], Powers, Pyles, Sutter & Verville, Washington, DC; Peter D. Winebrake, Trujillo, Rodriguez & Richards, Philadelphia, PA, Counsel for Appellants.

Charles W. Scarborough [ARGUED], U.S. Department of Justice, Appellate Section, Washington, DC; Mark B. Stern, U.S. Department of Justice, Civil Division, Appellate Staff, Washington, DC, Counsel for Appellee.

Stacy A. Fols, Montgomery, McCracken, Walker & Rhoads, Cherry Hill, NJ, Counsel for Amicus-appellants The National Association of Social Workers, Inc. and PA Chapter of the National Association of Social Workers.

M. Duncan Grant, Pepper Hamilton, Philadelphia, PA, Counsel for Amicus-appellant Program for Psychiatry and the Law at Harvard Medical School.

Jonathan S. Martel, Arnold & Porter, Washington, DC, Counsel for Amicus-appellant NARAL Pro-Choice America Foundation.

David P. Felsher, New York, NY, Counsel for Amicus-appellants Guenter L. Spanknebel, Leonard Morse, Wayne Glazier, Graham L. Spruiell, and Association of American Physicians and Surgeons, Inc.

JUDGES: Before: McKEE, RENDELL and NYGAARD **, Circuit Judges.

OPINION BY: RENDELL

OPINION: OPINION OF THE COURT

RENDELL, Circuit Judge.

Appellant Citizens for Health, along with nine other national and state associations and nine individuals (collectively "Citizens"), brought this action against the Secretary of the United States Department of Health and Human Services ("HHS" or "Agency") challenging a rule promulgated by the Agency pursuant to the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936. Citizens allege that the "Privacy Rule"-officially titled "Standards for Privacy of Individually Identifiable Health Information"-is invalid because it unlawfully authorizes health plans, health care clearinghouses, and certain health care providers to use and disclose personal health information for so-called "routine uses" without patient consent. The relevant part of the specific offending provision of the Privacy Rule reads:

> (a) Standard: Permitted uses and disclosures. Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) [relating to psychotherapy notes] and (3) [relating to marketing], a covered entity may use or disclose protected health information for treatment, payment, or health care operations . . . provided that such use or disclosure is consistent with other applicable requirements of this subpart.

> (b) Standard: Consent for uses and disclosures permitted. (1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.
>
> (2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

45 C.F.R. § 164.506 (emphasis added). Citizens challenge subsection (a) as authorizing disclosures that, they contend, violate individual privacy rights.

The District Court granted summary judgment to the Secretary on all of Citizens' claims based on its conclusions that the promulgation of the Privacy Rule did not violate the Administrative Procedure Act, that the Secretary did not exceed the scope of authority granted to him by HIPAA, and that, insofar as the Privacy Rule is permissive and does not compel any uses or disclosures of personal health information by providers, it does not affirmatively interfere with any right protected by the First or Fifth Amendments. Because we reason to the same conclusions reached by the District Court, albeit under a slightly different analysis, we will affirm.

I. Background

The objectionable provision is only one aspect of a

complex set of regulations that is the last in a series of attempts by HHS to strike a balance between two competing objectives of HIPAA-improving the efficiency and effectiveness of the national health care system and preserving individual privacy in personal health information.

A. HIPAA

HIPAA was passed by Congress in August 1996 to address a number of issues regarding the national health care and health insurance system. The statutory provisions relevant to the issues in this case are found in Subtitle F of Title II.[1] Aimed at "administrative simplification," HIPAA Sections 261 through 264 provide for "the establishment of standards and requirements for the electronic transmission of certain health information." § 261, 110 Stat. at 2021. More specifically, these provisions direct the Secretary to adopt uniform national standards for the secure electronic exchange of health information. § 262, 110 Stat. at 2021-26.

Section 264 prescribes the process by which standards regarding the privacy of individually identifiable health information were to be adopted. § 264(a), 110 Stat. at 2033. This process contemplated that, within a year of HIPAA's enactment, the Secretary would submit detailed recommendations on such privacy standards, including individual rights concerning individually identifiable health information, procedures for exercising such rights, and the "uses and disclosures of such information that should be authorized or required," to Congress. § 264(a)-(b), 110 Stat. at 2033. If Congress did not enact further legislation within three

years of HIPAA's enactment, the Secretary was directed to promulgate final regulations implementing the standards within 42 months of HIPAA's enactment. § 264(c)(1), 110 Stat. at 2033. The Act specified that any regulation promulgated pursuant to the authority of Section 264 would provide a federal baseline for privacy protection, but that such regulations would "not supercede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation." § 264(c)(2), 110 Stat. at 2033-34.[2]

B. The Privacy Rule

Because Congress did not enact privacy legislation by its self-imposed three-year deadline, the Secretary promulgated the privacy standards contemplated in Section 264 through an administrative rulemaking process. During this process, the Rule went through four iterations: the Proposed Original Rule, the Original Rule, the Proposed Amended Rule, and the Amended Rule.[3] The Original Rule required covered entities to seek individual consent before using or disclosing protected health information for routine uses. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,810 (Dec. 28, 2000) (codified at former 45 C.F.R. pts. 160, 164 (2002)). Before the Original Rule could take effect, however, the Secretary was inundated with unsolicited criticism, principally from health care insurers and providers, warning that the Original Rule's mandatory consent provisions would significantly impact the ability of the health care industry to operate efficiently.[4] Standards

for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 14,776, 14,777 (Mar. 27, 2002). He responded by reopening the rulemaking process. *Id.* at 14,776. The final result was the Amended Rule-the currently effective, codified version of the Privacy Rule, see generally 45 C.F.R. pts. 160 & 164, which is the subject of Citizens' challenge here.[5]

The Amended Rule retains most of the Original Rule's privacy protections. It prohibits "covered entities"[6]-defined as health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction covered by the regulations-from using or disclosing an individual's "protected health information"-defined as individually identifiable health information maintained in or transmitted in any form or media including electronic media-except as otherwise provided by the Rule. See 45 C.F.R. §§ 160.103 (defining "covered entities" and "protected health information"), 164.502(a) ("A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter."). Covered entities must seek authorization from individuals before using or disclosing information unless a specific exception applies. Id. § 164.508(a)(1) ("Authorization required: general rule. Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section."). Uses and disclosures that the Amended Rule allows must be limited to the "minimum necessary" to accomplish the intended purpose. Id. § 164.502(b).

The Amended Rule departs from the Original Rule in one crucial respect. Where the Original Rule required covered entities to seek individual consent to use or disclose health information in all but the narrowest of circumstances,[7] the Amended Rule allows such uses and disclosures without patient consent for "treatment, payment, and health care operations"-so-called "routine uses." Id. §§ 164.506 (providing routine use exception). "Health care operations," the broadest category under the routine use exception, refers to a range of management functions of covered entities, including quality assessment, practitioner evaluation, student training programs, insurance rating, auditing services, and business planning and development. Id. § 164.501. The Rule allows individuals the right to request restrictions on uses and disclosures of protected health information and to enter into agreements with covered entities regarding such restrictions, but does not require covered entities to abide by such requests or to agree to any restriction. Id. § 164.522(a). The Rule also permits, but does not require, covered entities to design and implement a consent process for routine uses and disclosures. Id. § 164.506; see also Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,211 (Aug. 14, 2002).

Importantly, the Rule contains detailed preemption provisions, which are consistent with HIPAA Sections 1178(a)(2)(B) and 264(c)(2). These provisions establish that the Rule is intended as a "federal floor" for privacy protection, allowing state law to control where a "provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or

implementation specification adopted under [the Privacy Rule]." 45 C.F.R. § 160.203 (emphasis added).[8]

II. Procedural History

Citizens filed this action on April 10, 2003. In its Amended Complaint, Citizens alleged that the Secretary violated the APA and Sections 261 through 264 of HIPAA in promulgating the Amended Rule, and that, to the extent that the Amended Rule rescinded or eliminated the need for consent for the use and disclosure of individually identifiable health information for "routine uses," the Amended Rule violated privacy rights protected by the Fifth Amendment and free speech rights protected by the First Amendment of the United States Constitution. *Citizens for Health v. Thompson*, No. 03-2267, 2004 U.S. Dist. LEXIS 5745, at *22 (E.D. Pa. Apr. 2, 2004). Both parties moved for summary judgment, and, after a hearing on December 10, 2003, the District Court granted summary judgment in favor of the Secretary. 2004 U.S. Dist. LEXIS 5745, at *2.

On Citizens' APA claims, the Court concluded that the Secretary had adequately informed the public regarding the proposed rulemaking, examined the relevant data, responded to public comments, and provided a reasoned analysis that rationally connected the facts with the decision to rescind the consent requirement in the Amended Rule. 2004 U.S. Dist. LEXIS 5745, at *33-43. Regarding Citizens' claims alleging violations of HIPAA, the Court concluded that the changes in the Amended Rule were reasonably related to the legislative purpose of Subtitle F of the Act, and, because the Amended Rule was promulgated

before the Original Rule took effect, the Amended Rule did not eliminate any "rights" created under the Original Rule. 2004 U.S. Dist. LEXIS 5745, at *43-46. Finally, regarding Citizens' constitutional claims, the Court concluded that because (1) neither the First Amendment nor the Fifth Amendment places an affirmative obligation on the State to protect individuals' rights from harm by third parties and (2) the Amended Rule is wholly permissive as to whether covered entities seek consent from an individual before using or disclosing personal health information for routine uses, the Amended Rule did not violate individual rights under either Amendment. 2004 U.S. Dist. LEXIS 5745, at *46-50.

III. Jurisdiction and Standard of Review

The District Court had jurisdiction under 28 U.S.C. § 1331, and we have jurisdiction to review the final decision of the District Court under 28 U.S.C. § 1291. We exercise plenary review over the District Court's grant of summary judgment, applying the same test as the District Court. *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976). To affirm the grant of summary judgment, we must be convinced that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law when the facts are viewed in the light most favorable to the nonmoving party. Fed. R. Civ. P. 56(c).

IV. Discussion

On appeal, Citizens reassert the claims they made before the District Court, that the Secretary, by promulgating the Privacy Rule, (1) unlawfully infringed

Citzens' fundamental rights to privacy in personal health information under due process principles of the Fifth Amendment of the United States Constitution; (2) unlawfully infringed Citzens' rights to communicate privately with their medical practitioners under the First Amendment of the Constitution; (3) contravened Congress's intent in enacting HIPAA by eliminating Citizens' reasonable expectations of medical privacy; and (4) violated the APA by arbitrarily and capriciously reversing a settled course of behavior and adopting a policy that he had previously rejected.

Before addressing Citizens' claims on the merits, we note that we raised the issue of justiciability at oral argument, and asked the parties for separate briefing on this issue. Our concern was that, in their complaint, the party plaintiffs do not recount specific instances of violations of their privacy rights traceable to the regulation, but, instead, complain of the regulation's general effect. After reviewing the parties' responses to our questions, however, we are satisfied that these specific instances do, in fact, exist, notwithstanding the general allegations in the complaint.[9] We therefore proceed to address each of Citizens' claims in turn.

A. Fifth Amendment Substantive Due Process Claim

In discussing Citizens' Fifth Amendment claim, the District Court noted that substantive due process bars the government from depriving individuals of life, liberty, or property without due process of law, but it does not "'impose an affirmative obligation on the State to ensure that those interests do not come to harm through other means.'" *Citizens for Health*, 2004 U.S. Dist. LEXIS 5745, at *46-47 (quoting *DeShaney v.*

Winnebago County Soc. Servs. Dep't, 489 U.S. 189, 195, 109 S. Ct. 998, 103 L. Ed. 2d 249 (1989)). Applying this principle to the case at hand, the Court reasoned that, even assuming that individuals have a constitutional right to medical privacy, the Amended Rule is "wholly permissive with respect to whether a covered entity should seek consent from a patient before using his or her information for routine purposes. The Amended Rule neither requires nor prohibits that practice." 2004 U.S. Dist. LEXIS 5745, at *47-48. In short, "because the Amended Rule is not compulsory in nature, it does not affirmatively interfere with any right." Id. We agree with the District Court that Citizens' constitutional claims should ultimately be resolved based on the nature of the state's involvement in light of the Amended Rule's permissive character. However, we think that the District Court's analysis does not go far enough, and that its reliance on DeShaney does not fully explain why Citizens cannot succeed here.

We begin our analysis with the premise that the right to medical privacy asserted by Citizens is legally cognizable under the Due Process Clause of the Fifth Amendment, although, as Citizens themselves concede, its "boundaries . . . have not been exhaustively delineated." (Appellants' Br. at 12.)[10] Whatever those boundaries may be, it is undisputed that a violation of a citizen's right to medical privacy rises to the level of a constitutional claim only when that violation can properly be ascribed to the government. The Constitution protects against state interference with fundamental rights. It only applies to restrict private behavior in limited circumstances. Because such circumstances are not present in this case, and because the "violations" of the right to medical privacy that

Citizens have asserted, if they amount to violations of that right at all, occurred at the hands of private entities, the protections of the Due Process Clause of the Fifth Amendment are not implicated in this case. We will accordingly affirm the District Court's finding that the Secretary did not violate Citizens' constitutional rights when he promulgated the Amended Rule.

"The Constitution structures the National Government, confines its actions, and, in regard to certain individual liberties and other specified matters, confines the actions of the States. With a few exceptions, . . . constitutional guarantees of individual liberty and equal protection do not apply to the actions of private entities." *Edmonson v. Leesville Concrete Co.*, 500 U.S. 614, 619, 111 S. Ct. 2077, 114 L. Ed. 2d 660 (1991). Indeed, it is well established that the substantive component of due process, embodied in both the Fifth and Fourteenth Amendments,[11] "'provides heightened protection against government interference with certain fundamental rights and liberty interests.'" *Troxel v. Granville*, 530 U.S. 57, 65, 120 S. Ct. 2054, 147 L. Ed. 2d 49 (2000) (quoting *Washington v. Glucksberg*, 521 U.S. 702, 720, 117 S. Ct. 2258, 117 S. Ct. 2302, 138 L. Ed. 2d 772 (1997)) (emphasis added); see also *Reno v. Flores*, 507 U.S. 292, 301, 113 S. Ct. 1439, 123 L. Ed. 2d 1 (1993). As explained in DeShaney, the Due Process Clauses of the Fifth and Fourteenth Amendments were intended to prevent federal and state governments "'from abusing [their] power, or employing it as an instrument of oppression.'" 489 U.S. at 196 (quoting *Davidson v. Cannon*, 474 U.S. 344, 348, 106 S. Ct. 668, 88 L. Ed. 2d 677 (1986)). Their "purpose was to protect

the people from the State, not to ensure that the State protected them from each other." Id.

At first glance, the posture of this case seems different from that of most state action cases. The issue of state action usually arises where plaintiffs assert that their rights have been violated by private parties who, they claim, are acting on behalf of the state. E.g., *Jackson v. Metro. Edison Co.*, 419 U.S. 345, 95 S. Ct. 449, 42 L. Ed. 2d 477 (1974) (customer suing private utility company for violation of procedural due process on the theory that the utility was a "state actor" by virtue of a state-granted monopoly and extensive state regulation). In this case, by contrast, the action that Citizens challenge-the promulgation of the Amended Rule by the Secretary-is clearly government conduct. As noted above, however, the injury that Citizens allege is that their "personal health information" is being "used and disclosed, without their permission and against their will" by third parties. (Appellants' Br. at 2.) To support their claims, Citizens point to privacy notices that they received from private health care providers and pharmacies. See *Citizens for Health*, 2004 U.S. Dist. LEXIS 5745, at *27-28. Citizens did not challenge any use or disclosure by the Secretary himself, or urge that the third parties were somehow acting on the Secretary's behalf, before the District Court.[12] The relevant question, then, is whether the Secretary, as a state actor, was sufficiently involved in producing the harm Citizens assert to satisfy the Constitution's state action requirement.

As noted above, the District Court touched on the state action issue when it applied DeShaney's holding that due process does not impose an affirmative obligation

on the State to protect individuals' interests in life, liberty, or property from harm inflicted by private actors. See 489 U.S. at 195. But the District Court's analysis in this respect was incomplete. Although the fundamental principle that due process protections apply only to prevent injury attributable to conduct of the State underlies the discussion in DeShaney, the Supreme Court's analysis in that case did not focus on "state action" as such. There, the Court was presented with a claim against a local government for its failure to prevent a father from physically abusing his son to the point of permanent injury where the local social services agency knew of the abuse but failed to remove the child from the father's custody. *Id.* at 191. Plaintiffs argued that the State was "categorically obligated" to protect the child from abuse and that, given this obligation, the State's failure to act was a proper basis for a due process challenge. *Id.* at 195. The Court's analysis thus sought to determine whether due process imposed a "duty" or "obligation" on the State to protect individuals from private harm, not "whether the State was sufficiently involved [in the privately caused harm] to treat that decisive conduct as state action." *Collegiate Athletic Ass'n v. Tarkanian*, 488 U.S. 179, 192, 109 S. Ct. 454, 102 L. Ed. 2d 469 (1988).

In this case, DeShaney helps resolve a preliminary question: Was the Secretary obliged to prohibit any and all disclosures without consent in order to protect privacy rights across the board? We think the District Court appropriately relied on DeShaney to answer that question in the negative. But DeShaney does not reach the specific question before us: Is the nonconsensual use or disclosure of individual health information by private parties, as permitted by the Amended Rule,

legally attributable to the Secretary? We conclude that it is not.

To answer this question, we must determine "whether there is a sufficiently close nexus between the State and the challenged action of the regulated entity [-the private party-] so that the action of the latter may fairly be treated as that of the State itself." *Jackson*, 419 U.S. at 351. Where, as here, plaintiff argues that the State has "authorized" or "empowered" a private entity to act in a way that directly brings about the alleged injury, our inquiry focuses on "whether the State provided a mantle of authority that enhanced the power of the harm-causing individual actor." *Tarkanian*, 488 U.S. at 192. Unfortunately, there is no "infallible test" to employ in this analysis. *Reitman v. Mulkey*, 387 U.S. 369, 378, 87 S. Ct. 1627, 18 L. Ed. 2d 830 (1967). Rather, it is "'only by sifting facts and weighing circumstances' on a case-by-case basis [that] a 'nonobvious involvement of the State in private conduct [can] be attributed its true significance.'" Id. (quoting *Burton v. Wilmington Parking Auth.*, 365 U.S. 715, 722, 81 S. Ct. 856, 6 L. Ed. 2d 45 (1961)).

The Supreme Court provided guidance as to what satisfies the Constitution's state action requirement in *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 90 S. Ct. 1598, 26 L. Ed. 2d 142 (1970). In that case, the Court explained that actions challenged on constitutional grounds fall somewhere along a continuum, with direct action by the State on one side and action by a "private party not acting against a backdrop of state compulsion or involvement" on the other. *Id.* at 168. Whereas the former meets the state action requirement for constitutional claims, the latter does not (although it

could form the basis for a claim on statutory or common law grounds, depending on the alleged violation). The Court further elaborated that, along this continuum, the enactment of a state law "requiring" violation of individual rights, and "enforcement" of such a law establish the requisite state action. *Id.* at 170. "[A] State is responsible for the discriminatory act of a private party when the State, by its law, has compelled the act" or when the State has "commanded" a particular result. Id. (emphasis added) (citing *Peterson v. City of Greenville*, 373 U.S. 244, 248, 83 S. Ct. 1119, 10 L. Ed. 2d 323 (1963); *Robinson v. Florida*, 378 U.S. 153, 84 S. Ct. 1693, 12 L. Ed. 2d 771 (1964); *Lombard v. Louisiana*, 373 U.S. 267, 83 S. Ct. 1122, 10 L. Ed. 2d 338 (1963); *Shuttlesworth v. Birmingham*, 373 U.S. 262, 83 S. Ct. 1130, 10 L. Ed. 2d 335 (1963)).

The first inquiry, then, is whether the Amended Rule can fairly be read to "require," "compel," or "command" routine use disclosures without consent. We conclude that it cannot. The fact that subsection (b) of the Rule expressly permits covered entities to obtain consent belies such an interpretation. See 45 C.F.R. § 164.506(b)(1) ("A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.") (emphasis added). Thus, the Amended Rule does not directly "provide a mantle of authority that enhance[s] the power of" health care providers and other entities, *Tarkanian*, 488 U.S. at 192.

Citizens argue that the Amended Rule's grant of "regulatory permission" to make the challenged uses and disclosures, see, e.g., 67 Fed. Reg. at 53,209, 53,211,

53,212 (discussing Amended Rule), indirectly provides the requisite "mantle of authority". To demonstrate a link between the Amended Rule and private parties' use and disclosure of Citizens' health information without their consent, Citizens point to two sources: (1) changes in the privacy policies of covered entities, and (2) evidence that some entities have begun ignoring applicable state privacy laws. On the first point, Citizens have identified at least one covered entity that has adopted a blanket policy of refusing all requests for restrictions on uses and disclosures of health information since the promulgation of the Amended Rule.[13] They further assert that some covered entities have simply ignored applicable, more restrictive, state laws in making such uses and disclosures.[14]

Our reading of the case law discussed below, however, leads us to the conclusion that the fact that a private party changed its behavior in response to a law does not give the law the coercive quality upon which the state action inquiry depends unless the law itself suddenly authorized something that was previously prohibited. Citizens' argument assumes (1) that covered entities were previously prohibited from making nonconsensual uses or disclosures for routine uses and (2) that the Amended Rule's "authorization" somehow permits uses or disclosures that were previously "unauthorized". But there is no authority for either proposition. Citizens have not shown that federal law prohibited nonconsensual uses or disclosures of health information before the Rule was promulgated.[15] And the preemption provisions of HIPAA and the Amended Rule expressly provide that any state statutes that prohibited such uses and disclosures before the Amended Rule was promulgated remain in effect.[16]

Because there is no indication that the nonconsensual uses and disclosures permitted by the Amended Rule were prohibited before the Rule went into effect, we have difficulty understanding how the Amended Rule "authorizes" covered entities to take action that they could not have otherwise taken. In the words of the *Tarkanian* test, Citizens have not shown how, by promulgating the Amended Rule, the Secretary "enhanced the power" of the covered entities to use or disclose health information without patients' consent; covered entities had this power already.

By way of analogy, assume that Congress were to pass legislation permitting private cinema operators, at their discretion, to search all moviegoers for any reason, without any showing of probable cause or reasonable suspicion. Although the Fourth Amendment would preclude the federal government from conducting such a search, private cinema operators are not bound by the Fourth Amendment, and absent any other law prohibiting it, private cinema operators were already "permitted" to conduct such a search before the new legislation took effect. To the extent that this new legislation changes the legal landscape at all, then, it only codifies a power that cinema operators had already. The codification does not transform the private exercise of the codified power into "state action." Similarly, although the codification itself is clearly government action, it seems insufficient to endow a moviegoer's challenge to a search by a cinema operator with constitutional significance given that the codification has neither enhanced nor diminished the individual moviegoer's rights.

None of the cases that Citizens or amici cite supports

the view that a government authorization of conduct that was already legally permissible satisfies the constitutional state action requirement. It is true that these cases find state action based on the enactment of statutes that permit private parties to infringe the constitutional rights of others.[17] But the laws that the Supreme Court has struck down in these cases allowed private parties to take some action (usually discrimination based on race) where they would otherwise have been prohibited from doing so. In other words, the Court found that the state, by enacting these laws, had "empowered" private parties to act in ways that would have been prohibited but for the enactment of the law. As we explained above, that is not the case here.

The Supreme Court's decision in *Reitman v. Mulkey*, 387 U.S. 369, 87 S. Ct. 1627, 18 L. Ed. 2d 830 (1967), illustrates this point. That case involved a constitutional challenge to an amendment to the California Constitution that allowed private persons absolute discretion to refuse to sell, lease, or rent property to another. The amendment effectively nullified California statutes that prohibited racial discrimination in private housing transactions. *Id.* at 374. The California Supreme Court reasoned that, because the State had taken affirmative action designed to make private discrimination legally possible-changing the situation from one in which private discrimination was restricted by statute to one in which it was encouraged-the State was at least a partner in the challenged discrimination. *Id.* at 375. The Court noted that the State could maintain a neutral position regarding private discrimination and was not bound by the Federal Constitution to forbid it. But once the State

acted in a way that encouraged private discrimination, even if it stopped short of mandating such action, it crossed the constitutional line. Id.

The United States Supreme Court affirmed the judgment of the California Supreme Court. The Court rejected petitioners' argument that the state court's reasoning was flawed because it meant that the mere repeal of a statute that prohibited private racial discrimination could be said to "authorize" or "encourage" discrimination simply because it permitted that which was formerly proscribed, pointing out that the challenged state action in case was not "the mere repeal" of prior anti-discrimination laws. *Id.* at 376. Rather, the offensive action was the state's authorization and "constitutionalization" (under the state constitution) of the previously forbidden private right to discriminate. Id. Consequently, the amendment had a much broader impact than the mere repeal of existing statutes:

> Private discriminations in housing were now not only free from [the previously enacted anti-discrimination statutes] but they also enjoyed a far different status than was true before the passage of those statutes. The right to discriminate, including the right to discriminate on racial grounds, was now embodied in the State's basic charter, immune from legislative, executive, or judicial regulation at any level of the state government. Those practicing racial discriminations need no longer rely solely on their personal choice. They could now invoke express [state] constitutional authority, free

> from censure or interference of any kind from official sources.

Id. at 380-81 (emphasis added).[18] In other words, the amendment was constitutionally offensive not only because it now permitted conduct that was previously prohibited, but also because it affirmatively protected such conduct under the state constitution.

The Reitman Court elaborated on this principle by referring to its ruling in *Nixon v. Condon*, 286 U.S. 73, 52 S. Ct. 484, 76 L. Ed. 984 (1932). It noted that, in Nixon,

> the Court was faced with a statute empowering the executive committee of a political party to prescribe the qualifications of its members for voting or for other participation, but containing no directions with respect to the exercise of that power. This was authority which the committee otherwise might not have had and which was used by the committee to bar Negroes from voting in primary elections. Reposing this power in the executive committee was said to insinuate the State into the self-regulatory, decision-making scheme of the voluntary association; the exercise of the power was viewed as an expression of state authority contrary to the Fourteenth Amendment.

Reitman, 387 U.S. at 379 (discussing Nixon) (emphasis added). As in Reitman, then, the Nixon Court found that the enactment of the statute satisfied the state action requirement because the challenged law provided the committee with a power that it "otherwise

might not have had." Id. Because the Amended Rule does not endow covered entities with any power that they did not have otherwise, the action of the Secretary that Citizens challenge does not fit the *Reitman / Nixon* mold.

The Amended Rule has not enhanced covered entities' power, under federal or state law, to use or disclose confidential health information without patients' consent. The Rule does not "compel" or "command" or "require" that private entities use information without patients' consent. See *Adickes*, 398 U.S. at 170. Nor has the Rule changed the situation from one in which nonconsensual routine uses and disclosures were prohibited to one in which they are now encouraged, see *Reitman*, 387 U.S. 369, 87 S. Ct. 1627, 18 L. Ed. 2d 830, or conferred authority on health care providers that they might not have had otherwise. See *Nixon*, 286 U.S. 73, 52 S. Ct. 484, 76 L. Ed. 984. Accordingly, we conclude that the Secretary's promulgation of the Amended Rule does not satisfy the Constitution's state action requirement.

The fact that covered entities are construing the "may use" language as constituting a new federal seal of approval, and may be ignoring state laws regarding protections to be afforded to such information, is regrettable and disquieting. That routine requests for privacy are apparently being ignored by covered entities is even more unfortunate. But our task here is to determine the constitutionality of the Amended Rule, not the propriety of covered entities' actions under state or common law. Because, for all of the reasons stated above, the covered entities' actions that Citizens challenge do not implicate the federal

government, we reject Citizens' Fifth Amendment claim.

B. First Amendment Claim

Citizens' First Amendment claim is that the Amended Rule infringes individuals' right to confidential communications with health care practitioners, i.e., a right to refrain from public speech regarding private personal health information. Citizens argue that the effect of the Amended Rule is to chill speech between individuals and their health care practitioners because the possibility of nonconsensual disclosures makes individuals less likely to participate fully in diagnosis and treatment and more likely to be evasive and withhold important information. Further, because the Rule applies to "health information . . . whether oral or recorded in any form or medium . . . ," 45 C.F.R. § 160.103, Citizens argue that the Rule is a content-based regulation reviewable under strict scrutiny.

We believe that a First Amendment claim is an ill-suited challenge to the Amended Rule. Cf. *South Carolina Med. Ass'n v. Thompson*, 327 F.3d 346, 355 n.4 (4th Cir. 2003) ("We summarily dispense with appellants' argument that the Privacy Rule will chill patients' rights of free speech, as we find this claim to be without merit."). The cases on which Citizens rely are not authoritative on the precise issue before us. See *Bartnicki v. Vopper*, 532 U.S. 514, 533, 121 S. Ct. 1753, 149 L. Ed. 2d 787 (2001) (suggesting that "the fear of public disclosure of private conversations might well have a chilling effect on private speech," but ultimately holding that any such interest was outweighed in that case by the media's countervailing First Amendment

interest in publishing truthful information of public concern); *Jaffee v. Redmond*, 518 U.S. 1, 11-12, 116 S. Ct. 1923, 135 L. Ed. 2d 337 (1996) (citing the "public interest" in confidential communications between a psychotherapist and her patient as justification for recognizing a psychotherapist-patient privilege in federal courts). And, more to the point, Citizens' First Amendment claim fails on the same grounds as their Fifth Amendment claim: the potential "chilling" of patients' rights to free speech derives not from any action of the government, but from the independent decisions of private parties with respect to the use and disclosure of individual health information. For all of the reasons enumerated above, the decisions of the private parties to use or disclose private health information in reliance on the Amended Rule, which may or may not "chill" expression between health care providers and their patients, does not implicate the government in a way that gives rise to a constitutional claim. We will therefore affirm the District Court's grant of summary judgment to the Secretary on Citizens' First Amendment claim.

C. Claims Alleging Violations of HIPAA

In claims based on HIPAA's statutory language, Citizens argue (1) that the Secretary exceeded the regulatory authority delegated by HIPAA because the Act only authorizes the Secretary to promulgate regulations that enhance privacy and (2) that the Amended Rule impermissibly retroactively rescinded individual rights created by the Original Rule and disturbed Citizens' "settled expectations" in the privacy of their health information. We find the District Court's analysis of these statutory claims to be cogent. Citizens

argue that the Secretary has eliminated their reasonable expectations of medical privacy retroactively and prospectively and that such action is inconsistent with Congress's intent in enacting HIPAA. However, Citizens' argument that the controlling policy underlying HIPAA is medical privacy and that the Amended Rule wholly sacrifices this interest to covered entities' interests in efficiency and flexibility ignores the Act's stated goals of "simplifying the administration of health insurance," HIPAA pmbl., 110 Stat. at 1936, and "improving the efficiency and effectiveness of the health care system," HIPAA § 261 (stating purpose of Subtitle F). As the District Court aptly explained, HIPAA requires the Secretary to "balance privacy protection and the efficiency of the health care system-not simply to enhance privacy." *Citizens for Health*, 2004 U.S. Dist. LEXIS 5745, at *43. We thus conclude that Citizens' first HIPAA claim lacks merit.

We also agree with the District Court's finding that the Amended Rule does not retroactively eliminate rights that Citizens enjoyed under the Original Rule or under various laws or standards of practice that existed before the Amended Rule went into effect. Because the Original Rule was amended before its compliance date, "covered entities were never under a legal obligation to comply with the Original Rule's consent requirement." 2004 U.S. Dist. LEXIS 5745, at *45-46. Citizens, therefore, never enjoyed any rights under the Original Rule at all. Nor does the Amended Rule retroactively eliminate Citizens' reasonable expectations based on state law, standards of medical ethics and established standards of practice because the Amended Rule does not disturb any preexisting, "more stringent" state law privacy rights. See 2004 U.S. Dist. LEXIS 5745, at *45-

46. See also Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,212 (Aug. 14, 2002) ("State laws that are more stringent [than the Privacy Rule] remain in place. In order not to interfere with such laws and ethical standards, this Rule permits covered entities to obtain consent. Nor is the Privacy Rule intended to serve as a 'best practices' standard. Thus, professional standards that are more protective of privacy retain their vitality." (emphasis added)). Accordingly, we reject Citizens' second HIPPA claim as well, and will affirm the grant of summary judgment to the Secretary on these claims.

D. APA Claims

Lastly, Citizens challenge the rulemaking process under the APA, contending that (1) the Secretary's rulemaking was arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A), and (2) the Secretary failed to provide adequate notice of the rescission of the consent requirement of the Original Rule, a violation of 5 U.S.C. § 553(b)(3). Citizens argue that the Secretary acted arbitrarily and capriciously by failing to adequately explain the rescission of the consent requirement, ignoring earlier findings, and failing to respond to public comments.

We dispose of Citizens' argument that the Secretary did not provide adequate notice to the public of his intention to rescind the consent requirement first. On this point, the District Court correctly pointed out that the APA requires a notice to provide either "the terms or substance of the proposed rule" or "a description of the subjects and issues involved." *Citizens for Health,*

*2004 U.S. Dist. LEXIS 5745, at *42-43* (quoting 5 U.S.C. § 553(b)(3)). In this case, the Notice for Proposed Rulemaking did both. See Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 14,776, 14,810-14,815 (Mar. 27, 2002) (setting forth the language of the Proposed Amended Rule); id. at 14,778-14,783 (describing the subjects and issues involved in the proposed modification). We will therefore affirm the District Court's grant of summary judgment to the Secretary on this claim.

We also reject Citizens' claim that the Secretary acted arbitrarily and capriciously in promulgating the Amended Rule. Citizens argue that the Secretary acted arbitrarily and capriciously in promulgating the Amended Rule by improperly reversing a "settled course of behavior" established in the Original Rule and adopting a policy that he had previously rejected. When an agency rejects a "settled course of behavior," however, it need only supply a "reasoned analysis" for the change to overcome any presumption that the settled rule best carries out the policies committed to the agency by Congress. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41-42, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983) (quoting *Atchison, T. & S. F. R. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 807-08, 93 S. Ct. 2367, 37 L. Ed. 2d 350 (1973)). Such an analysis requires the agency to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* at 43 (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168, 83 S. Ct. 239, 9 L. Ed. 2d 207 (1962)).

Here, the Secretary examined the relevant data, see

Citizens for Public Health, 2004 U.S. Dist. LEXIS 5745, at *39-41, and gave adequate consideration to the large volume of public comments that HHS received during the rulemaking process. 2004 U.S. Dist. LEXIS 5745, at *41-42. The Secretary considered other alternatives and explained why they were unworkable. 2004 U.S. Dist. LEXIS 5745, at *35-38. The Secretary also considered Congress's dual goals in devising the privacy standards, i.e., protecting the confidentiality of personal health information and improving the efficiency and effectiveness of the national health care system. 2004 U.S. Dist. LEXIS 5745, at *41-42.

In sum, the Secretary's decision to respond to the unintended negative effects and administrative burdens of the Original Rule by rescinding the consent requirement for routine uses and implementing more stringent notice requirements was explained in a detailed analysis that rationally connected the decision to the facts. "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." 2004 U.S. Dist. LEXIS 5745, at *43. The Secretary has not failed in any of these respects, and, hence, we agree with the District Court's analysis and conclusion that the Secretary's decision was reasonable given the findings and that the Secretary did not act arbitrarily and capriciously in violation of the APA. Accordingly, we will affirm the grant of summary judgment to the Secretary on these claims.

V. Conclusion

For the reasons set forth above, we will AFFIRM the judgment of the District Court.

Footnotes

* Amended Per Court's Order dated 2/4/05 Pursuant to F.R.A.P. 43(c)(2)

** Since the date of argument Judge Nygaard has assumed senior status.

n1 HIPAA Title II, Subtitle F comprises sections 261 through 264. Section 261, codified at 42 U.S.C. § 1320d note, states the purpose of the Subtitle. Section 262 amends Title XI of the Social Security Act, 42 U.S.C. § 1301 et seq., to add Part C, "Administrative Simplification," with sections 1171-1179, codified at 42 U.S.C. §§ 1320d to 1320d-8. Section 263 amends the Public Health Service Act at 42 U.S.C. § 242k(k). Section 264, discussed infra, is codified at 42 U.S.C. § 1320d-2 note. See *S.C. Med. Ass'n v. Thompson*, 327 F.3d 346, 348 n.1 (4th Cir. 2003) (explaining effect of HIPAA administrative simplification provisions).

n2 Section 264(c)(2) is cross-referenced in HIPAA § 1178, which provides that HIPAA generally preempts provisions of state law except, inter alia, where a provision of state law, "subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information." § 1178(a)(2)(B), 110 Stat. at 2030.

n3 The District Court explored the regulatory history of the Privacy Rule in detail. See *Citizens for Health v. Thompson*, No. 03-2267, 2004 U.S. Dist. LEXIS 5745, at *6-21 (E.D. Pa. Apr. 2, 2004). Because our decision here turns mostly on the effect of the Rule as amended, we have chosen not to repeat that discussion here.

n4 According to the Secretary, some of the "more significant examples and concerns" that commenters raised in connection with the Original Rule were that the prior consent requirement for routine disclosures would bar pharmacists from filling prescriptions and searching for potential drug interactions before patients arrived at the pharmacy, it would interfere with the practice of emergency medicine in cases where it would be difficult or impossible to obtain patient consent before treatment, and it would delay the scheduling of and preparation for hospital procedures until the patient provided the required consent. Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,209 (Aug. 14, 2002).

n5 The Amended Rule took effect on April 14, 2003, the same date that had been set for compliance with the Original Rule. 45 C.F.R. § 164.534.

n6 The statutory language, as well as the Rule, limits the applicability of the provisions of the Rule to "covered entities". See HIPAA § 262(a) (amending § 1172(a) of the Social Security Act) (codified at 42 U.S.C. § 1320d-1).

n7 Health care providers who had indirect treatment relationships with an individual and those who created

or received health information in the course of treating inmate patients were exempt from the Original Rule's consent requirement. 65 Fed. Reg. 82,462, 82,810. In addition, the Original Rule allowed providers to proceed without consent in situations where they had a legal obligation to provide treatment and attempts to obtain consent had failed, e.g., in emergency situations, or where a provider's attempts to obtain explicit consent were thwarted by a substantial communication barrier, but the provider could properly infer such consent from the circumstances. Id.

n8 The regulations define the following terms with the following meanings:

> "More stringent" means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under [the Privacy Rule], a State law that meets one or more of the following criteria:
>
> (1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:
>
> (i) Required by the Secretary in connection with determining whether a covered entity is in compliance with this subchapter; or
>
> (ii) To the individual who is the subject of

the individually identifiable health information.

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information. "Relates to the privacy of individually identifiable health information "

> means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way. "State law" means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

45 C.F.R. § 160.202.

n9 To satisfy Article III's justiciability requirement, "plaintiffs must demonstrate that they have suffered an injury-in-fact, that the injury is causally connected and traceable to an action of the defendant, and that it is redressable." *Pitt News v. Fisher*, 215 F.3d 354, 359 (3d Cir. 2000) (citing *Doe v. Nat'l Bd. of Med. Exam'rs*, 199 F.3d 146, 152-53 (3d Cir. 1999)). To support his or her standing at the summary judgment stage, "plaintiff . . . must 'set forth' by affidavit or other evidence 'specific facts' . . . which for purposes of the summary judgment motion will be taken to be true." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992) (quoting Fed. R. Civ. P. 56(e)). A plaintiff satisfies the injury-in-fact prong of the justiciability requirement where he or she alleges an injury that affects him or her "in a personal and individual way." *Id.* at 561 n.1. We agree with the District Court that Citizens have met this burden through affidavits, letters, and other documentary evidence demonstrating that at least one individual plaintiff's health information has been, or will imminently be, disclosed without her consent by private health care providers and drugstore chains, and that she and her family will avoid seeking medical care to prevent further disclosures of medical

information without their consent. See *Citizens for Health*, 2004 U.S. Dist. LEXIS 5745, at *27-30. An injury is redressable for justiciability purposes where plaintiff can show that "it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 181, 120 S. Ct. 693, 145 L. Ed. 2d 610 (2000). According to Citizens' affidavits, at least one individual plaintiff had successfully restricted the use of her health information before the Privacy Rule took effect on April 14, 1003. *Citizens for Health*, 2004 U.S. Dist. LEXIS 5745, at *27. Accepting these facts as true, as we must at this stage in the litigation, it follows that invalidating the Privacy Rule is likely to redress her alleged injury by restoring the status quo ante.

With respect to the "traceability" prong of the justiciability requirement, we conclude that Citizens' alleged injury is traceable to the promulgation of the Privacy Rule for two reasons. First, notices that plaintiffs received from covered entities such as Kaiser Permanente, Eckerd Drugs and Genovese Drugs, and Blue Cross/Blue Shield of Delaware explain the entities' intent to use and disclose plaintiffs' health information without consent (i.e., the sources of the alleged injury at the heart of this case) using language lifted directly from the Privacy Rule itself. Second, plaintiff's statement in her affidavit that her ability to restrict the use and disclosure of her health information changed after April 14, 2003, the Privacy Rule's effective date, *Citizens for Health*, 2004 U.S. Dist. LEXIS 5745, at *28-30, implies that the Rule is a "cause in fact" of her alleged injury.

We emphasize that, as justiciability is a "threshold" matter, *Pitt News*, 215 F.3d at 360, our analysis for these purposes is distinct from our analysis of the merits of plaintiffs' claims. As a result, our determination that Citizens' alleged injuries are "fairly traceable" to the Secretary's promulgation of the Privacy Rule and that rescission of the Rule is likely to redress plaintiffs' alleged injuries in no way amounts to a determination that the decisions of private entities to disclose or use plaintiffs' health care information without their consent are legally attributable to the federal government in such a way as to constitute state action. See *id.* at 361 n.4. In fact, we reach the opposite conclusion below.

n10 We express no opinion here on the scope of the federal constitutional right to medical privacy, or on whether the injury asserted by Citizens, if it were directly attributable to a state actor, would amount to a constitutional violation. Citizens assert in their brief that "the right . . . to not have [ones'] personal and identifiable health information made public or disclosed to numerous government employees in routine situations is a fundamental right implicit in the concept of ordered liberty and deeply rooted in the Nation's history." (Appellants' Br. at 20.) But the question of the scope of the constitutional right to privacy in one's medical information is largely unresolved. See, e.g., *Whalen v. Roe*, 429 U.S. 589, 602, 97 S. Ct. 869, 51 L. Ed. 2d 64 (1977) (recognizing that, despite constitutionally protected interest in avoiding disclosure of personal matters, "disclosures of private medical information to doctors, to hospital personnel, to insurance companies, and to public health agencies are

often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient"); *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 578 (3d Cir. 1980) ("The right of an individual to control access to his or her medical history is not absolute."). And, although Citizens contend that "governmental intrusions" on the right to privacy are subject to "heightened scrutiny," the standard of review we would apply would depend on the specific nature of the asserted violation. See *Fraternal Order of Police v. City of Philadelphia*, 812 F.2d 105, 110 (3d Cir. 1987) ("Most circuits appear to apply an 'intermediate standard of review' for the majority of confidentiality violations, . . . with a compelling interest analysis reserved for 'severe intrusions' on confidentiality." (citations omitted)). Because we conclude that Citizens' claims are more appropriately resolved through application of the state action doctrine, we do not decide these difficult questions now.

n11 In a due process claim brought under the Fifth Amendment, the "State" in the state action analysis is the federal government. See *Malloy v. Hogan*, 378 U.S. 1, 26, 84 S. Ct. 1489, 12 L. Ed. 2d 653 (1964) ("'Due process of law is secured against invasion by the federal Government by the Fifth Amendment, and is safeguarded against state action in identical words by the Fourteenth.'") (quoting *Betts v. Brady*, 316 U.S. 455, 462, 62 S. Ct. 1252, 86 L. Ed. 1595 (1942)); see also *Public Utilities Comm'n v. Pollak*, 343 U.S. 451, 461-62, 72 S. Ct. 813, 96 L. Ed. 1068 (1952).

n12 To be sure, Citizens and amici curiae have referred to other actions on the part of the federal government

besides the promulgation of the Amended Rule that they believe violate the Fifth Amendment in their arguments before this court. For instance, they argue in their briefs that, as the supervisor of a number of federal programs that qualify as "health plans" under HIPAA-including Medicare, Medicaid, and the Indian Health Services Programs-under the Amended Rule, HHS could make disclosures of protected health information as a covered entity. (Amici Supp. Br. at 6.) However, Citizens here challenge the Secretary's promulgation of the Privacy Rule, not specific disclosures by HHS or any of the federal agency "health plans" that it supervises. Whether a challenge to such specific disclosures would satisfy the Constitution's state action requirement thus remains outside the scope of this appeal.

n13 (See Appellants' Br. at 26 (quoting Kaiser Permanente's Notice of Privacy Practices ("You may request that we limit our uses and disclosures of your [personal health information] for treatment, payment, and health care operations purposes. However, by law, we do not have to agree to your request. Because we strongly believe that this information is needed to appropriately manage the care of our members/patients, it is our policy to not agree to requests for restrictions.")).)

n14 Citizens noted in their Reply Brief:

> As Plaintiffs noted at oral argument before the District Court, covered entities in Pennsylvania and Delaware are using and disclosing Plaintiffs' health information without consent under the authority granted by the Amended Rule despite

> a Delaware law that prohibits such disclosures without "informed consent of the individual" and a Pennsylvania law that deems it "unprofessional conduct" and a licensure violation for a licensed health professional to "depart from or fail[] to conform to an ethical or quality standard of the profession."

(Appellants' Reply Br. at 6 n.7 (citations omitted).) We note that, to the extent that these contentions are accurate, Citizens are free to pursue these covered entities directly under state law. That private entities are violating Citizens' state statutory rights does not in any way imply that the Secretary has violated Citizens' constitutional rights.

n15 Citizens rely on Federal Rule of Evidence 501 and the recognition of common law evidentiary privileges establishing special treatment for such information to establish that the uses and disclosures "authorized" by the Rule were prohibited before its promulgation. (Appellants' Reply Br. at 15.) But the Rule of Evidence and the common law of privilege are just evidentiary rules. They are not Acts of Congress or regulations that prohibit disclosure outside of court proceedings or otherwise provide Citizens with some affirmative "right" against disclosure of their information by private parties without their consent.

n16 Citizens contend that a number of otherwise "more stringent" state laws provide exceptions for disclosures that are "authorized" or "permitted" by federal law. (See Appellants' Reply Br. at 13-14 & n.9.) Whether or not that is the case, the fact remains that the Secretary has repeatedly emphasized that the Privacy Rule defers to

states that impose stringent consent requirements. See, e.g., Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,212 (Aug. 14, 2002) ("The Privacy Rule provides a federal floor of privacy protection. State laws that are more stringent remain in force."); Notice of Proposed Rulemaking, Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,997 (Nov. 3, 1999) ("We recognize that many State laws require patients to authorize or consent to disclosures of their health information for treatment and/or payment purposes. We consider individual authorization generally to be more protective of privacy interests than the lack of such authorization, so such State requirements would generally stand . . . ."). We take the Secretary's assurances that the Privacy Rule leaves pre-existing state law privacy rights in place at face value, particularly in light of the express non-preemption provisions for "more stringent" state laws in HIPAA and the Privacy Rule. As such, we do not read the Rule to "authorize" or "permit" disclosures that state laws would otherwise prohibit. Cf. *Fidelity Federal Sav. & Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 154, 102 S. Ct. 3014, 73 L. Ed. 2d 664 (1982) ("When the administrator promulgates regulations intended to pre-empt state law, the court's inquiry is . . . limited: 'If his choice represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned.'" (quoting United States v. Shimer, 367 U.S. 374, 383, 81 S. Ct. 1554, 6 L. Ed. 2d 908 (1961)).

n17 (Amicus Br. of Texas Civil Rights Project at 11-14 (citing *Reitman v. Mulkey*, 387 U.S. 369, 87 S. Ct. 1627, 18 L. Ed. 2d 830 (1967) (California Constitution could not provide that all persons have the absolute discretion to refuse to sell, lease, or rent property to another); *Gilmore v. City of Montgomery*, 417 U.S. 556, 94 S. Ct. 2416, 41 L. Ed. 2d 304 (1974) (city could not allow private groups to use and control city facilities where those private groups could deny access to the facility on the basis of race); *Nixon v. Condon*, 286 U.S. 73, 52 S. Ct. 484, 76 L. Ed. 984 (1932) (state statute could not permit political parties to deny party membership on the basis of race); *McCabe v. Atchison, Topeka, & Santa Fe Railway Co.*, 235 U.S. 151, 35 S. Ct. 69, 59 L. Ed. 169 (1914) (state statute could not permit railway to provide accommodations for Caucasian patrons, but not African American patrons)).)

n18 The Court reiterated this reasoning at the conclusion of the majority opinion:

> Here we are dealing with a provision which does not just repeal an existing law forbidding private racial discriminations. [The amendment] was intended to authorize, and does authorize, racial discrimination in the housing market. The right to discriminate is now one of the basic policies of the State. The California Supreme Court believes that the [amendment] will significantly encourage and involve the State in private discriminations. We have been presented with no persuasive considerations indicating that these judgments should be overturned.

Reitman, 387 U.S. at 380-81.

CIVIL ACTION NO. 03-2267

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CITIZENS FOR HEALTH, et al.,
Plaintiffs

v.

TOMMY G. THOMPSON, Secretary U.S. Department of Health and Human Services,
Defendant

April 2, 2004, Decided

COUNSEL: For CITIZENS FOR HEALTH, AMERICAN ASSOCIATION FOR HEALTH FREEDOM, AMERICAN ASSOCIATION OF PRACTICING PSYCHIATRISTS, AMERICAN MENTAL HEALTH ALLIANCE-USA, AMERICAN PSYCHOANALYTIC ASSOCIATION, NATIONAL COALITION OF MENTAL HEALTH PROFESSIONALS AND CONSUMERS, NEW HAMPSHIRE CITIZENS FOR HEALTH FREEDOM, SALLY SCOFIELD, TED KOREN, DC, MICHAELE DUNLAP, PSY.D., MORTON ZIVAN, PH.D., Plaintiffs: JAMES C. PYLES, POWERS PYLES SUTTER AND VERVILLE, P.C., WASHINGTON, DC. PETER D. WINEBRAKE, TRUJILLO RODRIQUEZ & RICHARDS, PHILADELPHIA, PA.

For CALIFORNIA CONSUMER HEALTHCARE COUNCIL, CONGRESS OF CALIFORNIA SENIORS, HEALTH ADMINISTRATION RESPONSIBILITY PROJECT, DANIEL S. SHRAGER, EUGENE B. MEYER, JANE DOE, Plaintiffs: PETER D. WINEBRAKE, TRUJILLO RODRIQUEZ & RICHARDS, PHILADELPHIA, PA.

For JANIS CHESTER, DEBORAH PEEL, Intervenor Plaintiffs: KENNETH I. TRUJILLO, PETER D. WINEBRAKE, TRUJILLO RODRIQUEZ & RICHARDS, PHILADELPHIA, PA. JAMES C. PYLES, POWERS PYLES SUTTER AND VERVILLE, P.C., WASHINGTON, DC.

For TOMMY G. THOMPSON, SECRETARY U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant: JAMES J. GILLIGAN, U.S. DEPARTMENT OF JUSTICE, CIVIL DIVISION, WASHINGTON, DC.

JUDGES: MARY A. McLAUGHLIN, J.

OPINIONBY: MARY A. McLAUGHLIN

OPINION:

MEMORANDUM AND ORDER

McLaughlin, J.

April 2, 2004

This action is brought by ten national and state associations, seven individuals and two individual intervenors against the Secretary of the United States

Department of Health and Human Services (the "Secretary"). The plaintiffs seek to invalidate an amended rule governing certain uses of individuals' identifiable health information that the Secretary promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936.

Under the prior version of the challenged rule, certain health care entities had to first obtain a person's consent before using and disclosing that person's identifiable health information for certain routine purposes. The plaintiffs challenge the amended rule to the extent it makes seeking consent optional. The parties have filed cross-motions for summary judgment. The Court heard oral argument on December 10, 2003. The Court will grant the defendant's motion and will deny the plaintiffs' motion.

I. Background

The Amended Rule is the fourth in a series of proposed and final rules issued by the Secretary between November 1999 and August 2002. Following is a list of the proposed and final rules, their dates of issuance, and their location in the Federal Register:

1. The rule as first proposed (the "Proposed Original Rule") was published as "Notice of Proposed Rule Making, Standards for Privacy of Individually Identifiable Health Information." *64 Fed. Reg. 59,918* (proposed Nov. 3, 1999) (the "1999 NPRM").

2. A final rule (the "Original Rule") was published as "Standards for Privacy of Individually Identifiable Health Information." *65 Fed. Reg. 82,462 (Dec. 28, 2000)* (codified at former 45 C.F.R. pts. 160, 164 (2002)).

3. A proposed amended version of the rule (the "Proposed Amended Rule") was published as "Notice of Proposed Rule Making, Standards for Privacy of Individually Identifiable Health Information." *67 Fed. Reg. 14,778* (proposed Mar. 27, 2002) (the "2002 NPRM").

4. The final version of the amended rule (the "Amended Rule") was published as "Final Rule, Standards for Privacy of Individually Identifiable Health Information," *67 Fed. Reg. 53,182 (Aug. 14, 2002)*, and codified as Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

The Court discusses below each of the four rules. All of the material comes from HIPAA or the Federal Register.

A. Statutory Framework

On August 21, 1996, the President signed HIPAA into law. HIPAA is organized into five titles. [1] The challenged rule was enacted pursuant to Title II. There were two goals of Title II: to prevent health care fraud and abuse; and to reduce the costs and administrative burdens of health care by replacing the many non-standard formats used nationally with a single set of electronic standards. It is the second goal with which we are concerned here.

In Title II, Congress sought to make the health care industry more efficient and effective. Congress looked to the adoption of uniform data standards in using electronic technology critical to reach this goal. Subtitle F of Title II, therefore, contains provisions intended to ensure that there are standards for the electronic transmission of financial and administrative data. HIPAA § § 261-262(a).

Subtitle F directed the Secretary: (1) to adopt standards and data elements for the electronic exchange of individually identifiable health information in connection with the delivery of, and payment for, health care services; and (2) to adopt standards for the security, integrity, and confidentiality of electronically stored or transmitted health care information. HIPAA § 262(a); *42 U.S.C. § 1320d-2.*[2]

Congress, through Subtitle F, also directed the Secretary to submit to Congress, within twelve months of HIPAA's enactment, recommendations on standards with respect to the privacy of health information, to be developed in consultation with the National Committee on Vital and Health Statistics ("NCVHS"). HIPPA § 264(a). These recommendations had to address: (1) the rights that an individual who is the subject of individually identifiable health information should have; (2) the procedures that should be established for the exercise of such rights; and (3) the uses and disclosures of such information that should be authorized or required. HIPAA § 264(b). If Congress failed to enact privacy standards within three years of the statute's enactment, the Secretary was to do so. HIPAA § 264(c)(1).

B. The Privacy Rule and its Evolution

When Congress did not enact privacy legislation by the third anniversary of HIPAA's enactment, the Secretary started the rulemaking process that resulted in the challenged rule.

1. The Proposed Original Rule

The Secretary issued the Proposed Original Rule on November 3, 1999. Covered health care providers and health plans were prohibited from using or disclosing

protected health information except as provided by the rule. Protected health information was defined as individually identifiable health information maintained in or transmitted in any form or media including electronic media.[3] See 1999 NPRM, *64 Fed. Reg. at 59,918, 59,927, 59,924, 59,939.*

The Proposed Original Rule listed the purposes for which protected health information could be used or disclosed without authorization and those purposes for which authorization was required. Authorization was not required for: routine uses; and uses for certain public-policy purposes, including public health, research, health oversight, law enforcement, and judicial proceedings.[4] 1999 NPRM, *64 Fed. Reg. at 60,053, 60,056-60,057* (text of then proposed *45 C.F.R. § § 164.506, 164.510*). For any purpose not recognized by the rule, covered entities had to obtain authorizations that had to include, among other things, a description of to whom and for what purpose the information would be disclosed, and a statement informing individuals of their right to revoke the authorization. *Id. at 60,055-60,056* (text of then proposed *45 C.F.R. § 164.508*).

It is the routine use provision that is at issue in this lawsuit. The proposed rule would have permitted covered entities to use or disclose individual health information, without patient authorization or consent, for treatment, payment and health care operations. This was in part because treatment and payment were considered core functions of the health care system for which people expect their health information will be used. Health care operations were deemed to be activities directly related to the core functions of treatment and payment, such as quality assurance, reviews of health care providers, underwriting,

auditing, fraud detection, or legal proceedings.[5] *Id. at 59,924, 59,933-59,934, 59,940, 60,052-60,054.*

The proposed rule prohibited covered entities from seeking individual authorization for these routine purposes, unless state or other applicable law required it. The Secretary reasoned that authorizations for these purposes could not provide meaningful privacy protections or individual control and could cause individuals to misunderstand what their rights and protections actually were. *Id. at 59,941.*

The Proposed Original Rule would have given individuals the right to receive from covered entities a notice of information practices, informing them about the permitted uses and disclosures the entities intended to make of the information. Covered entities would have been required to limit their uses or disclosures to those reflected in their notices. *Id. at 59,926, 59,945, 59,978.*

According to the Secretary, the notice was also meant to advise individuals of their right under the rule to request restrictions on the uses or disclosures of their health information. A covered entity would not have been required to agree to such a request, but if it did so, it would have to abide by the agreed to limitations. Id.

The standards in the Proposed Original Rule were described as creating "a federal floor of privacy protection." That is, they were not meant to supercede state or other applicable laws that provide more stringent privacy protections. *Id. at 59,926.*

2. The Original Rule

The Original Rule kept the structure of the proposed rule.[6] The most significant difference between the Proposed Original Rule and the Original Rule concerned consent. Consent for the use and disclosure of health information drew the most comments.[7] *65 Fed. Reg. at 82,472.* The Secretary adopted a consent requirement in the Original Rule for the routine uses of health information as follows:

> (a) Standard: Consent Requirement. (1) Except as provided in paragraph (a)(2) or (a)(3) of this section, a covered health care provider must obtain the individual's consent, in accordance with this section, prior to using or disclosing protected health information to carry out treatment, payment, or health care operations.

65 Fed. Reg. at 82,810 (text of former *45 C.F.R. § 164.506(a)(1)*).

The forms used to obtain consent had to: (1) include a general statement that protected health information may be used for routine purposes; (2) refer patients to the provider's notice of privacy practices; (3) inform patients of their right to request restrictions on the use and disclosure of their health information; and (4) inform individuals of their right to revoke this consent at any time. Covered health providers could refuse to treat patients who refused to give their consent in these situations. *65 Fed. Reg. at 82,810* (text of former *45 C.F.R. § § 164.506(b)-(c)*).

Subsection *(a)(2)* permitted certain covered health care providers to use health information for routine purposes without consent: providers who had an indirect treatment relationship with the patient; and

those who created or received the health information in the course of treating an inmate patient. Id. (text of former *45 C.F.R. § 164.506(a)*).

Subsection *(a)(3)* provided three other situations under which covered health care providers did not have to obtain consent from a patient before a routine use or disclosure of the patient's protected health information. First, no prior consent was needed in emergency treatment situations so long as consent was sought as soon as reasonably practicable after the emergency treatment. Second, consent was not required if the provider was required by law to treat the individual and had attempted, but was unable, to obtain his or her consent. Third, prior consent was unnecessary if the provider attempted to obtain consent of the patient, was unable to do so because of "substantial barriers to communicating," and, in the professional judgment of the provider, the patient's consent could clearly be inferred from the circumstances.[8] Id.

Covered health care providers had to comply with the Original Rule by April 14, 2003.[9] Covered providers would have been permitted to use or disclose health information created or obtained prior to the compliance date based on consent obtained prior to that date. This was true even where the consent did not meet the formal requirements of the Original Rule. In the absence of pre-existing consent, use of health information created or obtained prior to April 14, 2003, would be prohibited. *65 Fed. Reg. at 82,828* (text of former *45 C.F.R. § 164.532(a)-(b)*).

As with the Proposed Original Rule, the Original Rule preempted contrary state law only to the extent that the rule provided more privacy protections than the state law. *65 Fed. Reg. at 82,800-82,801* (text of former *45 C.F.R. § 160.203(b)*).

3. The Proposed Amended Rule

After publication of the Original Rule, the Secretary received many inquiries and unsolicited comments about the impact and operation of the Original Rule on numerous sectors of the health care industry regarding the rule's complexity and practicability. On February 28, 2001, the Secretary solicited additional public comment on the Original Rule. A purpose for the additional comment period was "to ensure that the provisions of the Privacy Rule would protect patients' privacy without creating unanticipated consequences that might harm patients' access to health care or quality of health care . . . . " 2002 NPRM, *67 Fed. Reg. at 14,777*; see also Request for Comments, *66 Fed. Reg. 12,738* (Feb. 28, 2001).

Many of the comments received discussed the potential adverse effects that the consent provisions would have on access to, and delivery of, health care services. The NCVHS also held public hearings that elicited public testimony on certain provisions, including consent. According to the Secretary, these comments and testimony prompted him to propose several modifications to the Original Rule, including the consent requirement. *2002 NPRM, 67 Fed. Reg. at 14,777.*

On March 27, 2002, the Secretary proposed to amend the Original Rule. The Proposed Amended Rule rescinded the consent requirement by granting covered

entities regulatory permission to use health information for routine purposes. Covered entities would no longer be required to obtain consent before using health information for treatment, payment, or health care operations. Providers, however, would be permitted to seek consent if and in any manner they chose. Additionally, the Amended Rule would require direct treatment providers to make good-faith efforts to obtain patients' written acknowledgment that they received the notice of privacy practices. *Id. at 14,777, 14,780, 14,783.*

The comment period on the Proposed Amended Rule ran from March 27, 2002 to April 26, 2002. During that period the Secretary received over 11,400 comments which were primarily devoted to the subject of consent. *67 Fed. Reg. at 53,183.*

The Secretary found that many comments supported the elimination of the consent requirement. Many other comments urged the Secretary to require consent, but to "make targeted fixes to address workability issues." Some comments sought a stronger consent requirement. *Id. at 53,210.*

According to the Secretary, many covered entities were concerned about, or had experienced significant practical problems with, the delivery of timely health care under the Original Rule. Pharmacists, for example, were concerned that they would be unable to fill prescriptions, search for potential drug interactions, determine eligibility or verify coverage before an individual arrived to pick up a prescription if the individual had not already provided consent. Hospitals would not have been able to use information from referring doctors to schedule and prepare procedures

before the patient arrived there. Emergency medical providers were concerned that attempting to seek consent prior to treatment in some situations was inconsistent with appropriate emergency care. The requirement that they seek consent as soon as reasonably practicable after an emergency greatly increased their administrative burden and could be viewed as harassment by the individuals. For the most part, these commenters supported rescission of the consent requirement. *Id. at 53,209.*

Some commenters were concerned that the Proposed Amended Rule would eliminate an important consumer protection, and that rescission of the consent requirement was too radical. They suggested targeted fixes to the practical problems caused by the requirement. *Id. at 53,210-53,211.* For example, some suggested to allow certain uses and disclosures prior to first patient encounters. Others suggested expanding the definition of health care providers with indirect treatment relationships to include pharmacists. Others proposed permitting oral or telephonic consent. *Id. at 53,211-53,212.*

A few commenters urged the Secretary to strengthen the consent requirement. For example, some commenters suggested that health plans as well as health care providers be covered by the requirement. *Id. at 53,212.*

4. The Amended Rule

The Secretary decided that, in light of the record, incorporating targeted fixes would require adding additional complexity to the rule. The Secretary claimed that a global approach to resolving the problems raised by the consent requirement was

consistent with one of the basic goals of the rule, namely, to provide necessary flexibility for the standards to work for the entire health care system. The Secretary therefore promulgated the Amended Rule with the provisions that he had proposed, thereby eliminating the consent requirement. Id.

The removal of the consent requirement applied only to uses or disclosures for treatment, payment or health care operations. *Section 164.506*, the provision that formerly contained the consent requirement, now reads in relevant part as follows:

> (a) Standard: Permitted uses and disclosures. Except with respect to uses or disclosures that require an authorization under *§ 164.508(a)(2)* [relating to psychotherapy notes] and (3) [relating to marketing], a covered entity may use or disclose protected health information for treatment, payment, or health care operations . . . provided that such use or disclosure is consistent with other applicable requirements of this subpart.
>
> (b) Standard: Consent for uses and disclosures permitted. (1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.
>
> (2) Consent under paragraph (b) of this section, shall not be effective to permit use or disclosure of protected health information when an authorization ... is required or when another

> condition must be met for such use and disclosure to be permitted under this subpart.

45. C.F.R. § 164.506.

The Amended Rule otherwise retained almost all the other protections and provisions of the Original Rule. In particular, authorization is still required for any uses not otherwise permitted by the Amended Rule. Individuals retain their right to request additional restrictions, and covered plans or providers that agree to these restrictions are still required to abide by those restrictions. Covered entities are still required to ensure that their business associates are under contract to abide by the same restrictions as they are. Provisions regarding uses and disclosures of identifiable health information for public-policy-related purposes were unaffected by the rescission of the consent requirement, because consent for such uses was not required by the Original Rule. See *67 Fed. Reg. at 53,211; 45 C.F.R. § § 164.504, 164.508, 164.522(a).*

Like the Original Rule, the Amended Rule generally preempts contrary State law. State law, however, will not be preempted if it provides a more stringent standard for protecting the privacy of individually identifiable health information. *45 C.F.R. § 160.203.*

The compliance date of the Amended Rule was April 14, 2003, the same as that of the Original Rule. *45 C.F.R. § 164.534.* Unlike the Original Rule, however, the Amended Rule applies to health information created or obtained prior to the compliance date. This means that health information created or obtained prior to April 14, 2003, may be used and disclosed after that

date for routine purposes without prior consent. *67 Fed. Reg. at 53,211.*

C. The Plaintiffs

The plaintiffs consist of nine individuals, including two intervenors, and ten organizations. Of the nine individuals, four are health care consumers and five are practicing mental health care providers some of whom are also health care consumers. Of the ten organizational plaintiffs, three are primarily health care consumer organizations with over 600,000 members collectively, another three are primarily mental health care provider organizations with over 5,000 members in total, and four are coalitions of health care providers, consumers and advocates. Am. Compl. PP 18-27.

The plaintiffs claim that the Secretary violated the *Administrative Procedure Act ("APA")* in promulgating the Amended Rule. They also claim that, to the extent it rescinds or eliminates the consent requirement regarding use and disclosure of an individual's health information for routine purposes, the Amended Rule violates: privacy and property rights guaranteed by the Fourth, Fifth, and *Ninth Amendments of the United States Constitution*; rights protected by the *First Amendment of the United States Constitution*; and the federal common-law therapist-patient privilege. The plaintiffs do not challenge other amendments to the rule, or those portions of the rule that have not been amended.

D. The Motions

In their motion for summary judgment, the plaintiffs argue that the Secretary's rescission of the consent requirement for routine uses was "arbitrary and capricious," was in excess of his statutory authority,

and violated various constitutional rights. The plaintiffs also argue that the Secretary gave inadequate public notice of his intent to rescind the consent requirement, provided an insufficient comment period for the Amended Rule, and promulgated an impermissibly retroactive rule by permitting the Amended Rule to apply to records created prior to the rule's compliance date.

The defendant contests all of these claims, and also argues that the plaintiffs do not have standing.

In support of their motion, the plaintiffs submitted selected comments from the administrative record, over twenty affidavits and supplemental affidavits, numerous privacy notices sent pursuant to the Amended Rule, and excerpts from HIPAA, the Federal Register, and miscellaneous policy statements.

In their affidavits, the plaintiffs allege various injuries caused by the Amended Rule's rescission of the consent requirement: (1) an elimination of the ability to know of and prevent or limit routine use and disclosure of health information necessary for current or future care; (2) an elimination of the ability to know of and prevent or limit routine use of health care information already in the hands of covered entities; (3) an erosion of patient's trust in health care providers; (4) a chilling effect on communications between patients and health care providers; and (5) an impairment of health care providers' ability to deliver effective psychotherapy services.

The Secretary provided the Court with a copy of the administrative record compiled in connection with the promulgation of the Amended Rule. This record includes: (1) forty-eight volumes of hard copy comments

submitted in response to the 2002 NPRM; (2) a CD-ROM containing public comments filed via email in response to 2002 NPRM; and (3) a CD-ROM containing public comments filed in response to the February 28, 2001, request for comments after the Original Rule had been adopted. The Secretary also submitted three volumes of excerpts from the administrative record.

II. Discussion

The Court cannot reach the merits of the plaintiffs' arguments if they do not have standing. *ACLU-NJ v. Township of Wall, 246 F.3d 258, 261 (3d Cir. 2001).* The Court, therefore, shall address this issue first. Because the Court finds that at least one of the plaintiffs has standing, the Court will then examine the plaintiffs' claims that the Secretary violated the APA by acting in an arbitrary and capricious manner in rulemaking and by failing to provide adequate notice that the Original Rule would be rescinded. The Court will also consider whether the Secretary violated the scope of authority granted by HIPAA, and whether the Amended rule was retroactive. Finally, the Court will examine the plaintiffs' constitutional claims.

A. Standing

There are three constitutional requirements that a plaintiff must meet in order to have standing to sue. First, the plaintiff must demonstrate an injury in fact. Second, there must be a causal connection between the plaintiff's injury and the defendant's conduct. Third, the relief requested must be likely to redress the injury suffered by the plaintiff.[10] See *Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 771, 146 L. Ed. 2d 836, 120 S. Ct. 1858 (2002)*; *Lujan v.*

Defenders of Wildlife, 504 U.S. 555, 560-61, 119 L. Ed. 2d 351, 112 S. Ct. 2130 (1992).

The plaintiffs have submitted numerous affidavits, asserting that they have suffered various injuries as a result of the Amended Rule and that rescission of the rule will redress those injuries.[11] The Court concludes that at least Dr. Deborah Peel has standing. Because the Court may reach the merits of the case if at least one plaintiff has standing, the Court will not examine the standing of the other plaintiffs.

Dr. Peel, an intervenor, is a practicing psychiatrist who alleges harm to herself and her family as health care consumers. She submitted three affidavits to the Court. She listed ten providers from which she and/or her family received privacy notices after the April 14, 2003, compliance date. The privacy notices are not identical. Some state that the practice "uses and discloses" health information for routine purposes. Others state that the practice "may use and disclose" that information for routine purposes without a patient's authorization. Others state that the practice "will use and disclose" health information for routine purposes. All of the notices stated that Dr. Peel had the right to request additional restrictions on the use and disclosure of her protected health information.

Dr. Peel requested such restrictions from a variety of these health care providers. She specifically lists three pharmacies that have refused her request not to disclose or use her information without her consent. No provider has acted favorably on any of her requests yet. She states that prior to April 14, 2003, she had been able to obtain restrictions on the use of her information.

Dr. Peel and her family are now limiting what information they give to their health care providers. She will avoid medical care for herself and her family except in dire situations. Dr. Peel states that these measures, however, cannot protect information that she and her family have disclosed in the past.

As a practitioner psychiatrist, Dr. Peel now has several patients who refuse to take their medications in an effort to shield their information from being used and disclosed by pharmacies. She believes that many more patients will avoid needed psychiatric care.

1. Injury in Fact

To have Article III standing, Dr. Peel must first demonstrate that she has suffered an injury in fact. This injury must be concrete and particularized, and actual or imminent, as opposed to conjectural or hypothetical. *Defenders of Wildlife, 504 U.S. at 560.* "The injury must affect the plaintiff in a personal and individual way." *Id. at 561 n.1.*

Dr. Peel has demonstrated a personal stake in the outcome of this litigation. Three health care providers have refused to grant her request to limit disclosure of the health information of her and her family. Others have not responded to her request; but, the notices they sent state that they will routinely disclose her health information.

The Secretary argued that Dr. Peel has not suffered injury in fact as to either information that she gave to providers prior to the effective date of the rule or information that she may be asked to provide in the future. As to information provided in the past, the Secretary argued that Dr. Peel has not shown any specific disclosure of her health information. As to the

future, the Secretary contends that Dr. Peel can limit what information she gives to providers or can cease treatment altogether with providers who will not agree to seek her consent before disclosing her health information for routine purposes. The Court is not persuaded by these arguments.

As to information provided in the past, a plaintiff does not have to show that the injury has occurred. It is enough to show that injury is imminent or highly likely to occur. See *Defenders of Wildlife, 504 U.S. at 564 n.2.* Dr. Peel has shown that here. She has received many notices from providers telling her that they are using her health information for routine purposes. On April 14, 2003, she received a notice that stated: "This practice uses and discloses health information about you for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care you receive." Notice of Privacy Practices, Austin Internal Medicine Associates, L.L.P., Peel Aff. I. This language indicates that such information has already been, or will imminently be, disclosed without her consent. Under these circumstances, Dr. Peel has demonstrated injury in fact.

Even as to future health information, Dr. Peel has made a strong argument for injury in fact. It is true that, in the future, patients can limit what information they give to their providers or can cease treatment altogether with providers who will not agree not to disclose their information without their consent. It is also true that under the Original Rule, providers had the right to refuse to give treatment if the patient would not consent to disclosure for routine purposes. The Court, however, does not agree with the defendant that these facts negate any injury. The Amended Rule

has changed the landscape established by the Original Rule for the disclosure of health information for routine purposes. That fact does not mean that the change is in violation of law. But it does mean that Dr. Peel can challenge that change.

2. Causation

The next question is whether Dr. Peel's injury in fact is causally connected and traceable to an action of the defendant. See *Pitt News v. Fisher, 215 F.3d 354, 360 (3d Cir. 2000)* (citing *Doe v. Nat'l Bd. of Med. Exam'rs, 199 F.3d 146, 152-53 (3d Cir. 1999))*. The defendant argues that there is no causation and traceability because Dr. Peel's injuries are the result of independent choices made by third parties not before the Court -- health care providers. The defendant is correct that when, as here, the allegedly unlawful rule regulates the conduct of someone other than the plaintiff, the plaintiff will not have standing if his injury is the result of unfettered or independent choices of "third parties not before the court." *Simon v. E. Ky. Welfare Rights Org., 426 U.S. 26, 41-42, 48 L. Ed. 2d 450, 96 S. Ct. 1917 (1976)*; see *Bennett, 520 U.S. at 169*. There is causation, however, if the injury is "produced by determinative or coercive effect upon the action of someone else." *Bennett, 520 U.S. at 169*; see *Pitt News, 215 F.3d at 360-61*.

It is true that the providers are permitted by the rule to seek consent before using or disclosing Dr. Peel's health information. They have chosen not to do so. There is causation, however, because the Amended Rule has a sufficiently determinative or coercive effect on the action of the providers.

The impact of the Amended Rule on providers must be considered in the context of the Original Rule. The plaintiffs allege that the amendment of the Original Rule was illegal. They seek to have the Original Rule reinstated. Under the Original Rule, Dr. Peel's health care provider would have had to seek her consent before using her health information for routine purposes. Under the Amended Rule, it no longer does. The Amended Rule has changed the landscape established by the Original Rule in which decisions will be made by providers as to whether they will seek consent or agree to patients' demands for consent. In this situation, there is causation. See *Bennett, 520 U.S. at 169* (finding causation and, thus, that the plaintiffs had standing to sue a government agency that issued the non-binding opinion relied upon by a different government agency to enact regulations that injured the plaintiffs); see also *Pitt News, 215 F.3d at 360-61* (finding causation, and standing, when a newspaper sued the Attorney General for enforcing a law intended to encourage third party activity that harmed the newspapers).

3. Redressability

The third requirement for Article III standing is that "it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc., 528 U.S. 167, 181, 145 L. Ed. 2d 610, 120 S. Ct. 693 (2000)*. Dr. Peel has demonstrated that it is not "merely speculative" that vacating the Amended Rule and reinstating the Original Rule would redress Dr. Peel's alleged injury. The Original Rule prohibited covered entities from using or disclosing protected health

information for routine purposes without patient consent.

The Court finds that Dr. Peel does have Article III standing.

B. APA Claims

The plaintiffs argue that the Secretary's rulemaking was arbitrary and capricious, and that the Secretary failed to provide adequate notice of the rescission of the Original Rule.

1. The Arbitrary and Capricious Claim

The plaintiffs argue that the Secretary acted arbitrarily and capriciously by failing adequately to explain the rescission of the consent requirement, ignoring earlier findings, and failing to respond to public comments. An agency's action in promulgating standards may be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *5 U.S.C. § 706(2)(A)*; see *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 41, 77 L. Ed. 2d 443, 103 S. Ct. 2856 (1983)*. This standard also applies to the rescission of an existing regulatory standard.

An agency acts arbitrarily and capriciously if it rescinds a promulgated rule without providing a "reasoned analysis" for the change. *Id. at 41-42*; see *Fertilizer Inst. v. Browner, 163 F.3d 774, 778 (3d Cir. 1998)*. A reasoned analysis requires the Secretary to examine the relevant data and articulate a satisfactory explanation that shows a "rational connection between the facts found and the choice made." *Motor Vehicle, 463 U.S. at 43* (quoting *Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168, 9 L. Ed. 2d 207, 83 S.*

Ct. 239 (1962)). The Court is not supposed to substitute its own judgment for that of the Secretary. If the agency action is rational, based on a consideration of relevant factors, and within the scope of the statutory delegation of power, it may not be set aside. *Id. at 42-43*.

a. The Secretary's Explanation

The Secretary explained that the consent requirement in the Original Rule was added in an attempt to strike a balance between privacy concerns and the need to use certain health care information.[12] The Secretary stated that the consent requirement in the Original Rule responded to comments that consent provides individuals with a sense of control over how their information will be used, was a current practice of health care providers, and was expected by many patients. *2002 NPRM, 67 Fed. Reg. at 14,779*.

According to the Secretary, comments and inquiries received after the Original Rule was implemented revealed many unintended consequences of the consent requirement. The comments received after the Amended Rule was proposed indicated that the consent requirement represented a significant change in practice and could substantially impair delivery of health care. The consent requirement could have also deprived providers and plans of information necessary for quality assurance, accreditation, and fraud and waste detection. *67 Fed. Reg. at 53,214*.

The Secretary then explained that rescinding the consent requirement solved the identified health care delivery problems caused by the requirement in the most efficient manner. According to the Secretary, incorporating targeted fixes as suggested by some

commenters would make the rule even more complex, without solving all of the problems. *Id. at 53,212.*

The Secretary added that all the other protections were left in place. In addition, the notice of privacy practices provision was strengthened to preserve the intended benefit of the consent requirement, that is, to provide patients with an opportunity to discuss privacy practices and concerns and to request restrictions on use and disclosure. *Id. at 53,209, 53,211.*

The plaintiffs rely on two cases in arguing that the Secretary's explanation is inadequate. In *Motor Vehicle, 103 S. Ct. at 2864,* the National Highway Traffic Safety Administration ("NHTSA") rescinded a regulation requiring new cars to be equipped with passive restraints, defined as either automatic seatbelts or airbags. The NHTSA determined that detachable automatic seatbelts would not be effective in attaining its safety goals, and so it rescinded the passive restraint requirement. The Supreme Court held that the NHTSA did not adequately explain the rescission. The NHTSA did not question that passive restraints were important to safety, but it never addressed why airbags, as one of the passive restraint options, could not serve the same safety functions. *Id. at 2869.* In short, there was no discussion of any alternatives available to the agency.

In Action on *Smoking and Health v. Civil Aeronautics Bd., 226 U.S. App. D.C. 57, 699 F.2d 1209, 1216 (D.C. Cir. 1983),* the Civil Aeronautics Board ("Board") rescinded and modified parts of a rule regulating smoking on aircraft. The Board's explanation of the rescission was contained in one brief paragraph that only concluded that carriers should have discretion

with respect to smoking on flights. The court held that the explanation was "palpably inadequate" because there was no reason for the Board's conclusion. Id.

The explanation of the rescission provided in the case at hand was much more detailed and is distinguishable from *Action on Smoking and Health* and *Motor Vehicle*. The Board in Action on Smoking and Health did not explain its reasons for rescinding the smoking regulations. The Secretary here, however, explained the rescission of the consent requirement in detail, as discussed above. With respect to the holding of Motor Vehicle, and in contrast to the explanation provided by the NHTSA in that case, the Secretary discussed possible alternatives and the reasons for the rescission. He determined that the rescission was the most efficient means to achieving the purposes set forth in HIPAA, § 261. The Secretary also explained why the alternative solutions would not be effective, or work at all. For these reasons, the Court finds that the Secretary's explanation was adequate and provided a reasoned analysis for the change.

b. Examination of the Relevant Data

The plaintiffs argue that the Secretary ignored the agency's earlier findings and thus did not establish a rational connection between agency findings supporting the Original Rule and the choice made in the Amended Rule. The Secretary, however, need only establish a rational connection between the most current findings and the changes to a rule. See *United States Air Tour Ass'n. v. Fed. Aviation Admin., 353 U.S. App. D.C. 213, 298 F.3d 997, 1007-08 (D.C. Cir. 2002).*

The Court reviewed the administrative record and finds that the Secretary used the agency's current

findings in explaining his rescission of the consent requirement. Based on the comments submitted during the comment period for the Proposed Amended Rule, the Secretary found that the consent requirement caused unintended inefficiencies in the delivery of health care. The Court's review of the record revealed that even some commenters who did not favor rescission acknowledged that there were unintended consequences that could hamper effective delivery of health care. See, e.g., Comments of the Amer. Counseling Ass'n, Pls.' Reply Br., App. II, at Tab 12.

Even if the Secretary had to reconcile past findings with the Amended Rule, the rescission of the consent requirement is not so inconsistent with earlier findings as to render the change so implausible that it could not be ascribed to a difference in viewpoint or the product of agency expertise. Contrary to the plaintiffs' suggestion, the agency never stated that the right to privacy was absolute when it implemented the Original Rule. Privacy concerns were always to be balanced against the goal of improving efficiency of the health care system. See *65 Fed. Reg. at 82,464.*

Indeed, the very findings that supported the Original Rule had supported the initial proposal to prohibit consent. According to the Secretary, the prohibition in the Proposed Original Rule was based on the undisputed finding that patient consent was frequently uninformed and involuntary. See *1999 NPRM, 64 Fed. Reg. at 59,940-59,941.* Consent in the Original Rule was required to provide patients with the opportunity to discuss privacy practices and request further restrictions. The Secretary explained that, far from ignoring the need to provide patients with this opportunity, the Amended Rule achieves the same goal

through its more stringent notice requirements. *67 Fed. Reg. at 53,256.*

The Court finds that the Secretary examined the relevant data and the Secretary's explanation shows more than a mere rational connection between the facts and the choice to rescind the consent requirement. He found that the requirement was impeding the ability of different sets of health care providers for different reasons. He considered alternatives to rescission but found that none of the alternatives would fix the problems for all health care providers. His decision to rescind was reasonable given these findings.

c. The Secretary's Response to Public Comments

The plaintiffs' argument that the Secretary failed adequately to respond to comments in the record is also unpersuasive. Agencies do not have to address every comment. They need only respond in a reasoned manner to comments raising significant problems. A failure to respond to comments is significant only insofar as it demonstrates that the decision was not based on relevant factors. See *City of Waukesha v. EPA, 355 U.S. App. D.C. 100, 320 F.3d 228, 257 (D.C. Cir. 2003).*

The Secretary's response to the comments revealed that he considered the relevant factors Congress intended the agency to consider. The two factors referred to in Subtitle F of HIPAA are the efficiency and effectiveness of the health care system, and the privacy of health information. See HIPAA § 261.

The Secretary justified the rescission of the consent requirement primarily because the requirement impeded efficient delivery of health care. The Secretary also took the privacy interests of patients into account

by permitting health care providers to obtain prior consent, in contrast with the Proposed Original Rule. He just balanced the factors in a way with which the plaintiffs disagree. The Secretary, in any event, responded to many comments that did not support rescission of the consent requirement, including those similar to the plaintiffs' argument that targeted fixes instead of rescission should be implemented. See *67 Fed. Reg. at 53,211-53,214.*

2. Notice of Rulemaking

The plaintiffs argue that the Secretary violated the APA because his notice of rulemaking did not adequately inform the public of his intention to rescind the consent requirement. A notice of proposed rulemaking must include either: (I) "the terms or substance of the proposed rule or;" (ii) "a description of the subjects and issues involved." *5 U.S.C. § 553(b)(3).*

The Secretary's notice for the Amended Rule did both. The notice of proposed rulemaking for the Amended Rule provided the text of the proposed amendments. See *2002 NPRM, 67 Fed. Reg. at 14,810-14,815.* The notice also described the proposed modification in detail, including the proposal to make consent optional for routine uses. See *id. at 14,780-14,781.*

C. Scope of Authority Granted by HIPAA

The plaintiffs argue that the Secretary exceeded the scope of authority granted to him by HIPAA in two ways. First, they claim that HIPAA authorizes the defendant to promulgate only regulations that enhance privacy. Second, they argue that the Amended Rule is retroactive in violation of HIPAA and the APA.

1. Reasonable Relationship of the Amended Rule to Statute

A regulation falls within the scope of statutory authority as long as it is reasonably related to the purposes of the enabling legislation. *Mourning v. Family Publ'ns Serv., Inc., 411 U.S. 356, 369, 36 L. Ed. 2d 318, 93 S. Ct. 1652 (1973).* Subtitle F of HIPAA Title II states that its purpose is "to improve . . . the efficiency and effectiveness of the health care system . . . through the establishment of standards and requirements for the electronic transmission of certain health information." HIPAA § 261.

Although HIPAA also required the Secretary to protect the privacy of health information, the Court finds nothing in the statute requiring the Secretary to maximize privacy interests over efficiency interests. His mandate is to balance privacy protection and the efficiency of the health care system -- not simply to enhance privacy.

The Court finds that the amendments to the Original Rule embodied in the Amended Rule are reasonably related to the legislative purpose of Subtitle F. The Secretary explained that he rescinded the consent requirement because it caused practical problems that interfered with the efficient delivery of health care. The Amended Rule kept all the other protections of the Original Rule and did nothing to remove more stringent protections afforded by state or other applicable law.

2. Retroactivity

A rule is retroactive if it impairs the rights already possessed when a person acted, or increases one's liability for past conduct, or imposes new duties with

respect to transactions already completed. *Landgraf v. USI Film Prods., 511 U.S. 244, 269-70, 280, 128 L. Ed. 2d 229, 114 S. Ct. 1483 (1994)*; see also *Avila-Macias v. Ashcroft, 328 F.3d 108, 113 (3d Cir. 2003)* (holding that the application of a new immigration act to a deportee who was removed before the passage of act, but who reentered after the passage of act, was not retroactive).

A rule is not retroactive just because it upsets expectations based on prior law. A new zoning regulation, for example, may upset the reasonable expectations that prompted the property owners to purchase the property. Likewise, a new law banning gambling may harm the person who had begun to construct a casino before the law's enactment. See *Landgraf, 511 U.S. at 270 n.24.*

According to the plaintiffs, individuals were vested with the right to give or withhold consent before their protected health information could be used for routine purposes once the Original Rule was implemented on April 14, 2001. The Original Rule, however, was amended before its April 14, 2003, compliance date. Covered entities were never under a legal obligation to comply with the Original Rule's consent requirement. Under these circumstances, the Original Rule did not create rights that were subsequently eliminated by the Amended Rule.

The plaintiffs also argue that the Amended Rule eliminates their reasonable expectations "based on federal and state law, standards of medical ethics and established standards of practice" that their health information created prior to the Amended Rule's compliance date would not be used for routine purposes without consent. But the Amended Rule does not

impair any stricter privacy rights created by state law, ethical codes or standards of practice. The Amended Rule is not retroactive.

C. Constitutional Claims

The plaintiffs claim that the Amended Rule violates Due Process rights to medical privacy, and *First Amendment* rights to private physician-patient communications. Because the Amended Rule does not compel anyone to use or disclose the plaintiffs' health information for routine purposes without the plaintiffs' consent, the Court finds that the Amended Rule does not violate the plaintiffs' constitutional rights.

The Due Process Clause forbids the government from depriving individuals of life, liberty, or property without due process of law. Generally, the clause does not "impose an affirmative obligation on the State to ensure that those interests do not come to harm through other means." *DeShaney v. Winnebago County Soc. Servs. Dep't, 489 U.S. 189, 195, 103 L. Ed. 2d 249, 109 S. Ct. 998 (1989).*

The *First Amendment* right to free speech is similarly framed. See *Alston v. Redman, 34 F.3d 1237, 1247 (3d Cir. 1994).* The government cannot place obstacles in the path of an individual's exercise of free speech, but it does not have to act to eliminate obstacles that it did not create. *Regan v. Taxation With Representation, 461 U.S. 540, 549-50, 76 L. Ed. 2d 129, 103 S. Ct. 1997 (1983)* (citing *Harris v. McRae, 448 U.S. 297, 316, 65 L. Ed. 2d 784, 100 S. Ct. 2671 (1980)).*

Even assuming that the plaintiffs have a constitutional right to privacy over their medical records and to patient-health care provider communications, the Amended Rule does not violate

those rights.[13] The Amended Rule is wholly permissive with respect to whether a covered entity should seek consent from a patient before using his or her information for routine purposes. The Amended Rule neither requires nor prohibits that practice.

Nor does the Amended Rule place obstacles in the paths of patients seeking to have confidential communications with their health care providers. The Amended Rule does not require doctors to do anything with respect to routine uses of health care information. Because the Amended Rule is not compulsory in nature, it does not affirmatively interfere with any right.[14]

To the extent the Amended Rule mandates any actions, it protects the plaintiffs' putative rights. For example, the Amended Rule prohibits covered entities from disclosing and using health information for reasons unrelated to health care without proper authorization.

In essence, the plaintiffs challenge the Amended Rule because the Secretary decided not to compel covered entities to obtain prior consent. The Constitution, however, does not command the Secretary to act affirmatively to protect such rights. See *DeShaney, 489 U.S. at 195*; *Alston, 34 F.3d at 1247*.

The plaintiffs have directed the Court's attention to recent cases that involve the attempts of the United States' Department of Justice ("DOJ") to subpoena or otherwise compel health care providers to produce the medical records of their patients who had undergone abortions. The DOJ has subpoenaed or sought court orders compelling the production of these medical

records in connection with a law suit challenging a federal law banning so-called "partial-birth abortions." See, e.g., Northwestern Mem'l Hosp. v. Ashcroft, No. 04-1379, *362 F.3d 923, 2004 U.S. App. LEXIS 5724 (3d Cir. Mar. 26, 2004)*.

The plaintiffs claim that these cases support their argument that the Amended Rule violates fundamental privacy rights. The Northwestern decision and the other DOJ cases cited by the plaintiff have no bearing on the plaintiffs' narrow challenge here. Those cases do not involve the disclosure of protected health information for routine purposes. They involve the disclosure of protected health information for other, nonroutine purposes. These disclosures are governed by provisions of the Amended Rule that the plaintiffs have not challenged.[15]

An appropriate Order follows.

ORDER

AND NOW, this 2nd day of April, 2004, upon consideration of the defendant's Motion for Summary Judgment (Docket No. 13), the plaintiffs' Motion for Summary Judgment (Docket No. 24), as well as all responses and replies thereto, and following oral argument on December 10, 2003, IT IS HEREBY ORDERED that the defendant's motion is GRANTED and the plaintiffs' motion is DENIED for the reasons stated in a memorandum of today's date. Judgment is entered in favor of the defendant and against the plaintiffs.

BY THE COURT:

MARY A. McLAUGHLIN, J.

Footnotes

n1 Title I focuses on the goal of permitting persons to qualify immediately for comparable health insurance coverage when they change employment by limiting waiting periods due to preexisting medical conditions. Title III contains tax-related provisions pertaining to medical savings accounts, increases for health insurance costs for the self-employed, and long-term care services and contracts. Title IV covers application and enforcement of group health plan requirements. Title V provides certain revenue offsets for the bill, including tax-provisions concerning company-owned life insurance and individuals who lose U.S. Citizenship.

n2 HIPAA § 262(a) adds a new part to Title XI of the Social Security Act, § § 1171-1179, codified at *42 U.S.C. § § 1320d to 1320d-8*. Where they exist, citations to the United States Code shall be used.

n3 "Health care provider" meant any person who furnishes, bills, or is paid for health care in the normal course of business. A "covered entity" includes a health care provider who transmitted any health information in electronic form. "Health information" meant any information whether oral or recorded in any form or medium that is created by health care providers (among others) and relates to any medical condition of, provision of health care to, and payment for such health care by, an individual. "Protected health information" meant individually identifiable health information maintained in or transmitted in any form or media including electronic media. *65 Fed. Reg. at 82,798-82,800, 82,803-82,805* (text of former *45 C.F.R. § §*

160.103, 164.501). These definitions remained constant throughout the rulemaking process.

n4 The proposed rule would have permitted a covered entity to disclose protected health information to its business partners -- entities that provided administrative, legal, accounting and other services -- only under a contract limiting the business partner to uses and disclosures of health information permitted to the covered entity under the rule. 1999 NPRM, *64 Fed. Reg. at 59,925*.

n5 Marketing, disclosure to a health plan or insurance company for enrollment determinations, or disclosure to an employer for hiring purposes did not qualify as health care operations for which use or disclosure without prior consent would be permitted. *Id. at 59,941*.

n6 The Original Rule adopted all of the following provisions of the Proposed Original rule: (1) that covered entities contract with their business associates to ensure that the latter would not use or disclose information in a way prohibited of the covered entity; (2) various individual rights to receive notices of privacy practices; (3) the right to request further restrictions on a covered entities uses and disclosures; (4) that covered entities are required to abide by any restrictions to which they agree. See *65 Fed. Reg. 82,808, 82,820, 82,822-82,823, 82,806* (text of former *45 C.F.R. § § 164.504(e), 164.520(a), 164.522(a), 164.502(c)*).

n7 The comment period for the 1999 NPRM began on November 3, 1999 and was originally scheduled to close 60 days later on January 3, 2000, but was extended to

February 17, 2000. Extension of Comment Period Notice, *65 Fed. Reg. 69,981* (Dec. 15, 1999).

n8 As with the Proposed Original Rule, the Original Rule also permitted all covered entities to use or disclose protected health information without prior authorization or consent for specified public policy-related purposes. *65 Fed. Reg. at 82,813-82,820* (text of former *45 C.F.R. § § 164.512, 164.514*).

n9 The initial compliance date was February 26, 2003. *65 Fed. Reg. at 82,829*. To comply with other statutory requirements, the compliance date was changed to April 14, 2003. See Correction of Effective and Compliance Dates, *66 Fed. Reg. 12,434* (Feb. 26, 2001); Original Rule, *45 C.F.R. § 164.534*.

n10 There are prudential restrictions on standing that a party must meet as well. See *Bennett v. Spear, 520 U.S. 154, 162, 137 L. Ed. 2d 281, 117 S. Ct. 1154 (1997)*. The defendant does not contend that these restrictions have not been met here. The Court independently concludes that the plaintiffs have met these restrictions.

n11 The party invoking federal jurisdiction bears the burden of establishing standing. Each element must be supported with the manner and degree of evidence required at the successive stages of litigation. At the summary judgment stage, the plaintiffs must produce affidavits or other evidence setting forth facts, which for purposes of summary judgement will be taken to be true. *Defenders of Wildlife, 504 U.S. at 561*.

n12 The Secretary twice provided detailed explanations for the rescission of the consent requirement. See *67 Fed. Reg. at 14,778-14,783*; *67 Fed. Reg. at 53,208-53,214*.

n13 The Court will not decide whether there are such constitutional rights.

n14 In this respect the Amended Rule is different from laws found unconstitutional in cases cited by the plaintiffs. The rule is unlike a rule giving third-parties absolute veto rights over decisions made by a doctor and patient. See *Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, 69, 49 L. Ed. 2d 788, 96 S. Ct. 2831 (1976).* The rule also is dissimilar to a rule requiring doctors who perform abortions to report personal details about their patients to state authorities. See *Thornburgh v. Am. Coll. of Obstetricians & Gynecologists, 476 U.S. 747, 765-68, 90 L. Ed. 2d 779, 106 S. Ct. 2169 (1986).*

n15 Indeed, *45 C.F.R. § 164.512(e)(1)(i)* of the Amended Rule does not modify the Original Rule at all. A party to a judicial proceeding could have similarly sought to compel health care providers to disclose health information without notice to or consent under the Original Rule. See *65 Fed. Reg. at 82,814-82,815* (text of former *45 C.F.R. § 164.512(e)(1)(i)*).

Filed 4/13/05
No. 04-2550
UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

CITIZENS FOR HEALTH; AMERICAN ASSOCIATION FOR HEALTH FREEDOM; AMERICAN ASSOCIATION OF PRACTICING PSYCHIATRISTS; AMERICAN MENTAL HEALTH ALLIANCE-USA; AMERICAN PSYCHOANALYTIC ASSOCIATION; NATIONAL COALITION OF MENTAL HEALTH PROFESSIONALS AND CONSUMERS; NEW HAMPSHIRE CITIZENS FOR HEALTH FREEDOM; SALLY SCOFIELD; TED KOREN, DC; MICHAELE DUNLAP, PSY.D.; MORTON ZIVAN, PH.D.; CALIFORNIA CONSUMER HEALTHCARE COUNCIL; CONGRESS OF CALIFORNIA SENIORS; HEALTH ADMINISTRATION RESPONSIBILITY PROJECT; DANIEL S. SHRAGER; EUGENE B. MEYER; JANE DOE; JANIS CHESTER; DEBORAH PEEL,

Appellants,

v.

* MICHAEL O. LEAVITT, SECRETARY U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

*Amended Per Court's Order dated 2/4/05 Pursuant to F.R.A.P. 43(c)(2)

Appeal from the United States District Court for the

Eastern District of Pennsylvania (D.C. Civil No. 03-cv-02267) District Judge: Honorable Mary A. McLaughliin

Present: SCIRICA, Chief Judge, SLOVITER, ALITO, ROTH McKEE, RENDELL BARRY, AMBRO, FUENTES SMITH, FISHER, and VAN ANTWERPEN and NYGAARD, * Circuit Judges;

SUR PETITION FOR REHEARING WITH SUGGESTION FOR REHEARING IN BANC

The petition for rehearing filed by Appellant having been submitted to all judges who participated in the decision of this court, and to all the other available circuit judges in active service, and a majority of the judges who concurred in the decision not having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court in banc, the petition for rehearing is hereby DENIED.

BY THE COURT:

/s/ Marjorie 0. Rendell
Circuit Judge

Dated; January 13, 2006
Robert N. Feltoon, Esq. James . Pyles, Esq. Peter D. Winebrake, Esq. David P. Felsher, Esq. Stacy A. Fols, Esq.
M. Duncan Grant, Esq. Jonathan S. Martel, Esq. Charles W.Scarborough, Esq. Mark B. Stern, Esq.

Footnotes

* Honorable Richard L. Nygaard, Senior Judge of the

United States Court of Appeals far the Third Circuit.
Judge Nygaard assumed senior status on July 9, 2005;
vote limited to panel rehearing.

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED IN THIS CASE

First Amendment to U.S. Constitution
Congress shall make no law...abridging freedom of speech...

Fourth Amendment to U.S. Constitution
The right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures, shall not be violated...

Fifth Amendment to the U.S. Constitution
No person shall... be deprived of life, liberty or property without due process of law; nor shall private property be taken for public use, without just compensation.

Ninth Amendment to the U.S. Constitution
The enumeration in the Constitution, of certain rights shall not be construed to deny or disparage others retained by the people.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)
Pub. L. 104-191, 110 Stat. 1936
Title II, Subsection F , Section 264

(a) In General.--Not later than the date that is 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Labor and Human Resources and the Committee on Finance of the Senate and the Committee on Commerce and the Committee on Ways and

Means of the House of Representatives detailed recommendations on the standards with respect to the privacy of individually identifiable health information.

(b) Subjects for Recommendations.—The recommendations under subsections (a) shall address at least the following:

(1) The rights that an individual who is the subject of individually identifiable health information should have.

(2) The procedures that should be established for the exercise of such rights.

(3) The uses and disclosures of such information that should be authorized or required.

(c) Regulations.—

(1) In General.—If legislation governing standards with respect to the privacy of individually identifiable health information...is not enacted by the date that is 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than the date that is 42 months after the date of the enactment of this Act. Such regulations shall address at least the subjects described in subsection (b).

Standards for Privacy of Individually Identifiable Health Information
45 C.F.R. 164.506(a), 65 Fed. Reg. at 82,810 (December 28, 2000)
(Original Rule)

Standard: Consent requirement. (1) Except as provided in paragraph (a)(2) or (a)(3) of this section, a covered

health care provider must obtain the individual's consent, in accordance with this section, prior to using or disclosing protected health information to carry out treatment, payment, or health care operations.

Standards for Privacy of Individually Identifiable Health Information
Preamble to 45 C.F.R. 164.506(a), 67 Fed. Reg. at 53,211 (August 14, 2002) (Amended Rule)
"The consent provisions in section 164.506 are replaced with a new provision at section 164.506(a) that provides regulatory permission for covered entities to use or disclose protected health information for treatment, payment, and health care operations."

45 C.F.R. 164.506(a), 67 Fed. Reg. at 53,268 (August 14, 2002)
Standard: Permitted uses and disclosures. Except with respect to uses or disclosures that require an authorization under section 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

FILED
JUN 14 2006
OFFICE OF THE CLERK
SUPREME COURT, U.S.

(3)

No. 05-1311

In the Supreme Court of the United States

CITIZENS FOR HEALTH, ET AL., PETITIONERS

v.

MICHAEL O. LEAVITT, SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

PAUL D. CLEMENT
Solicitor General
Counsel of Record

PETER D. KEISLER
Assistant Attorney General

MARK B. STERN
CHARLES W. SCARBOROUGH
Attorneys

Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

QUESTION PRESENTED

Whether the United States Department of Health and Human Services violated petitioners' asserted constitutional right to privacy in personal health information when it promulgated regulations that do not require treatment providers to obtain patient consent in order to use and disclose protected health information for certain routine purposes.

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In the Supreme Court of the United States

No. 05-1311

CITIZENS FOR HEALTH, ET AL., PETITIONERS

v.

MICHAEL O. LEAVITT, SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-42a) is reported at 428 F.3d 167. The opinion of the district court (Pet. App. 43a-80a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on October 31, 2005. A petition for rehearing was denied on January 13, 2006 (Pet. App. 81a-83a). The petition for a writ of certiorari was filed on April 13, 2006. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. In Title II, Subtitle F of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 2021, Congress sought to

improve "the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information." HIPAA § 261, 110 Stat. 2021 (42 U.S.C. 1320d note). To accomplish that goal, Congress instructed the Department of Health and Human Services (HHS) to adopt standards for unique identifiers, such as identifiers for health-care plans and health-care providers across the nation, and also to adopt standards for transactions and data elements relating to health information, the security of that information, and authentication of electronic signatures. HIPAA § 262, 110 Stat. 2024-2026 (42 U.S.C. 1320d-2).

Congress recognized that the new regulatory scheme posed risks to the privacy of confidential patient information by eroding practical barriers that historically had prevented improper access to that information. See H.R. Rep. No. 496, 104th Cong., 2d Sess. 99-100 (1996). Congress therefore directed HHS to submit "detailed recommendations on standards with respect to the privacy of individually identifiable health information" within one year after the statute's enactment. HIPAA § 264(a), 110 Stat. 2033 (42 U.S.C. 1320d-2 note). Congress specified that those recommendations should address "at least" three areas: (1) "[t]he rights that an individual who is a subject of individually identifiable health information should have," (2) "[t]he procedures that should be established for the exercise of such rights," and (3) "[t]he uses and disclosures of such information that should be authorized or required." HIPAA § 264(b), 110 Stat. 2033 (see 42 U.S.C. 1320d-2 note).

HIPAA further provided that, "[i]f legislation governing standards with respect to the privacy of individu-

ally identifiable health information" was not enacted within three years after HIPAA's enactment, HHS would be required to "promulgate final regulations containing such standards." HIPAA § 264(c)(1), 110 Stat. 2033 (see 42 U.S.C. 1320d-2 note). Under HIPAA, the privacy regulations adopted by HHS pursuant to that directive "shall not supercede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation." HIPAA § 264(c)(2), 110 Stat. 2033-2034 (see 42 U.S.C. 1320d-2 note).

2. No further legislation to protect the privacy of individually identifiable health information was enacted within the three-year period after HIPAA's enactment. To fulfill its responsibilities under HIPAA, HHS subsequently proposed and modified privacy standards that went through four major iterations. See 64 Fed. Reg. 59,918 (1999) (Proposed Original Rule); 65 Fed. Reg. 82,462 (2000) (Original Rule); 67 Fed. Reg. 14,776 (2002) (Proposed Amended Rule); 67 Fed. Reg. 53,182 (2002) (Final Amended Rule). As HHS explained, those standards sought to "improve the efficiency and effectiveness" of health-care services "by providing enhanced protections for individually identifiable health information." 64 Fed. Reg. at 59,918. The various iterations of the privacy rule generally prohibited health-care providers and other covered entities from using or disclosing protected health information, see *id.* at 59,924, while specifying certain circumstances in which the federal prohibition would not apply, see *id.* at 60,056-60,059 (allowing uses and disclosures for certain public policy pur-

poses, including research, health oversight, and law enforcement).

The Original Rule initially promulgated by HHS would generally have required health-care providers that directly treat patients to obtain patients' consent "prior to using or disclosing protected health information to carry out treatment, payment, or health care operations." 65 Fed. Reg. at 82,810 (text of former 45 C.F.R. 164.506(a)(1) (2002)). Before that requirement took effect, however, HHS received thousands of comments from covered entities explaining that a consent requirement for such "routine uses" of individual health information would significantly impair the health-care industry's ability to provide timely and efficient medical services. See 67 Fed. Reg. at 14,779 (summarizing public comments criticizing consent requirement). In response to those comments, HHS proposed several modifications to the Original Rule, see *id.* at 14,776, and ultimately promulgated a final rule that eliminated the consent requirement for routine uses, see *id.* at 53,182.

The Final Amended Rule expressly allows covered entities to seek consent to use or disclose information for routine uses if they choose to, see 45 C.F.R. 164.506, and it retains most of the specific privacy protections contained in the Original Rule, see 67 Fed. Reg. at 53,211. The Final Amended Rule also retains the general requirement that disclosures must be limited to the "minimum necessary" to accomplish the intended purpose. 45 C.F.R. 164.502(b). Consistent with HIPAA and earlier versions of the rule, the Final Amended Rule also provides that state law will not be preempted if it establishes more stringent standards for protecting the privacy of individually identifiable health information. 45 C.F.R. 160.203(b).

3. Petitioners are health-care providers, health-care organizations, and individuals. They filed suit against HHS in district court challenging the Final Amended Rule. Petitioners alleged that HHS had violated the Administrative Procedure Act (APA), 5 U.S.C. 553, 701-706, by failing to provide a reasoned explanation for its decision to eliminate the consent requirement for routine uses; that HHS had exceeded its authority under HIPAA by eliminating the consent requirement; and that HHS's decision not to require consent for routine uses violated petitioners' constitutional rights, including privacy rights protected by the Fifth Amendment and an asserted First Amendment right to engage in confidential physician-patient communications. See Pet. App. 9a, 57a.

On cross-motions for summary judgment, the district court upheld the Final Amended Rule in all respects. Pet. App. 43a-80a. After finding that at least some of the petitioners had standing to challenge the Final Amended Rule, *id.* at 59a-65a, the court held that HHS had provided a reasoned explanation for its decision to eliminate the consent requirement and had adequately examined and responded to the relevant data and public comments as required by the APA, *id.* at 65a-71a. The district court also held that the Final Amended Rule was within the scope of HHS's authority under HIPAA and that the rule was not impermissibly retroactive. *Id.* at 71a-74a. Finally, while assuming *arguendo* that petitioners had a constitutional right to privacy in their medical records, the court held that the Final Amended Rule did not violate such a right because the rule "is wholly permissive with respect to whether a covered entity should seek consent from a patient before using his or her information for routine purposes." *Id.* at 75a.

4. The court of appeals affirmed. Pet. App. 1a-42a. The court held that petitioners had established their standing to sue, *id.* at 34a n.9, and it assumed that petitioners had a constitutional right to privacy in their personal health information, *id.* at 36a n.10. Without defining the precise contours of that right, however, the court held that the privacy violations alleged by petitioners could not properly be ascribed to the government. *Id.* at 12a-13a. Noting that "the 'violations' of the right to medical privacy that [petitioners] have asserted, if they amount to violations of that right at all, occurred at the hands of private entities," the court concluded that "the protections of the Due Process Clause of the Fifth Amendment are not implicated in this case." *Ibid.*

The court of appeals observed that petitioners do "not challenge any use or disclosure [of private medical information] by the Secretary [of HHS] himself, or urge that the third parties were somehow acting on the Secretary's behalf." Pet. App. 14a. Rather, petitioners' constitutional claim is premised on the fact that "the nonconsensual use or disclosure of individual health information by private parties" is "permitted by the Amended Rule." *Id.* at 15a. Under those circumstances, the court stated, the relevant question is "whether the [government] provided a mantle of authority that enhanced the power of the harm-causing individual actor." *Id.* at 16a (quoting *NCAA* v. *Tarkanian*, 488 U.S. 179, 192 (1988)). The court found that petitioners could not make the requisite showing of affirmative governmental assistance in private disclosures because (1) there was no evidence that such disclosures had previously been forbidden by federal law, and (2) any state-law restrictions on disclosure of private health information remain

in force and are not preempted by HIPAA or the Amended Rule. *Id.* at 18a.

The court of appeals further explained that none of the state-action cases upon which petitioners relied "supports the view that a government authorization of conduct that was already legally permissible satisfies the constitutional state action requirement." Pet. App. 19a-20a. Because "[t]he Amended Rule has not enhanced covered entities' power, under federal or state law, to use or disclose confidential health information without patients' consent," *id.* at 23a, the court rejected petitioners' Fifth Amendment claim, *id.* at 23a-24a. The court rejected petitioners' First Amendment challenge for essentially the same reason, *id.* at 24a-25a, explaining that "the potential 'chilling' of patients' rights to free speech derives not from any action of the government, but from the independent decisions of private parties with respect to the use and disclosure of individual health information," *id.* at 25a.[1]

---

[1] The court of appeals also rejected petitioners' non-constitutional challenges to the Final Amended Rule. Pet. App. 25a-29a. The court noted that HIPAA requires HHS "to 'balance privacy protection and the efficiency of the health care system—not simply to enhance privacy,'" *id.* at 26a (citations omitted), and it held that the Final Amended Rule does not interfere with any reasonable expectations of privacy, particularly given the Rule's express preservation of any preexisting rights under state law, *ibid.* The court further held that HHS had acted reasonably by declining to include a consent requirement in the Final Amended Rule, explaining that the agency had examined the relevant data, fully considered the voluminous public comments on that issue, and adequately explained its decision. *Id.* at 28a-29a. Petitioners do not challenge those holdings in this Court.

ARGUMENT

The Final Amended Rule that is the subject of petitioners' constitutional challenge imposes restrictions on the use and disclosure of certain health information by private parties. It does not authorize or encourage any uses or disclosures that were not previously lawful, and it does not displace existing privacy protections. Petitioners contend that the government violated their rights under the First and Fifth Amendments by failing to require that certain health-care providers obtain patient consent before using or disclosing protected health information for specified purposes relating to such matters as treatment and payment. The court of appeals concluded that HHS's refusal to impose such a requirement did not provide a sufficient basis for attributing any subsequent private disclosures to the federal government. That holding is correct and does not conflict with any decision of this Court or of any other court of appeals. Further review is not warranted.

1. The Final Amended Rule establishes a comprehensive scheme under which covered entities are forbidden to use or disclose protected health information except as expressly authorized by the Rule. See 45 C.F.R. 164.502(a), 164.508. The Rule allows patients to request additional restrictions on the use or disclosure of their health information, which would then bind any covered entity that agreed to such limits, see 45 C.F.R. 164.522(a), and it generally restricts uses and disclosures to the "minimum necessary" to accomplish a permitted purpose, 45 C.F.R. 164.502(b). The Final Amended Rule thus provides enhanced federal protections for the privacy of individual health information.

Petitioners believe that additional use and disclosure restrictions are warranted. They contend that HHS should have retained an earlier version of the regulation that would have required certain health-care providers to obtain patient consent before using or disclosing protected health information for treatment, payment, or health-care operations. See Pet. 23-24. The Final Amended Rule does not require such consent. See 45 C.F.R. 164.506(a).

As the court of appeals recognized (see, *e.g.*, Pet. App. 15a-16a), HHS's decision not to prohibit certain private disclosures that petitioners find objectionable provides no basis for treating those disclosures as actions of the federal government. The Final Amended Rule does not compel any disclosures in connection with treatment, payment, or health-care operations. To the contrary, the Rule expressly allows covered entities to seek patients' consent for such uses or disclosures if the covered entity elects to do so. 45 C.F.R. 164.506(b). Nor does the Final Amended Rule supersede or displace "more stringent" privacy protections provided under state law. 45 C.F.R. 160.203(b). Rather, under the Final Amended Rule, patients retain whatever preexisting rights they may have had to prevent the use and disclosure of their protected health information.

2. While apparently recognizing that the Final Amended Rule does not *require* the disclosure of any private health information, petitioners contend that "state action is present where the federal government merely authorizes, encourages or endorses but does not compel or command" private conduct. Pet. 21. This Court's decisions make clear, however, that the government's mere failure to prohibit particular private conduct—even within a general sphere of activity that is

subject to "extensive state regulation"—is an insufficient basis for attributing that conduct to the government. See *American Mfrs. Mut. Ins. Co.* v. *Sullivan*, 526 U.S. 40, 52 (1999). Rather, state-action analysis "depends on whether the State has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the State. Action taken by private entities with the mere approval or acquiescence of the State is not state action." *Ibid.* (citations and internal quotation marks omitted).

In *American Manufacturers*, this Court reviewed a due process challenge to a Pennsylvania workers' compensation statute that allowed, but did not require, private insurers to withhold payments for disputed medical treatment pending "utilization review" of the claims. See 526 U.S. at 45-46. While acknowledging that "the State's decision to provide insurers the option of deferring payment for unnecessary and unreasonable treatment pending review can in some sense be seen as encouraging them to do just that," the Court explained that "this kind of subtle encouragement is no more significant than that which inheres in the State's creation or modification of any legal remedy." *Id.* at 53. The Court further observed that "[t]he State's decision to allow insurers to withhold payments pending review can just as easily be seen as state inaction." *Ibid.* The Court explained that, although the applicable statutory scheme "previously prohibited insurers from withholding payment for disputed medical services, it no longer does so. Such permission of a private choice cannot support a finding of state action." *Id.* at 54.

The same analysis applies here. Indeed, the argument for attributing the challenged private conduct to

the government is even weaker in this case than in *American Manufacturers*. That case involved a legislative change that removed preexisting restrictions on the freedom of private insurers to withhold payments pending resolution of disputes concerning the reasonableness of treatment. See 526 U.S. at 53-54. The regulations at issue here, by contrast, give covered entities no greater freedom to use or disclose health information than they possessed under prior law. See Pet. App. 18a.

3. Contrary to petitioners' contention (Pet. 21-28), the Third Circuit's decision in this case does not conflict with any precedent of this Court or of another court of appeals.

a. Petitioners' reliance (Pet. 20-21) on *Skinner* v. *Railway Labor Executives' Ass'n*, 489 U.S. 602 (1989), is misplaced. *Skinner* involved a Fourth Amendment challenge to drug and alcohol tests that were performed by railroads and were authorized but not compelled by federal regulations. The Court explained that "[w]hether a private party should be deemed an agent or instrument of the Government for Fourth Amendment purposes necessarily turns on the degree of the Government's participation in the private party's activities." *Id.* at 614. The Court observed that the federal regulations governing drug and alcohol testing of railroad employees "pre-empt[ed] state laws, rules, or regulations covering the same subject matter" and barred the railroads from divesting themselves by contract of the authority conferred by the regulations, thereby "remov[ing] all legal barriers to the testing." *Id.* at 615. The Court further concluded that the government, through its promulgation of the challenged regulations, had "made plain not only its strong preference for testing, but also its desire to share the fruits of such intru-

sions." *Ibid.* By contrast, the Final Amended Rule at issue in this case, which is challenged principally on substantive due process rather than Fourth Amendment grounds, does not preempt more stringent privacy protections under state law, see 45 C.F.R. 160.203(b); it expressly allows health-care providers to enter into agreements requiring patient consent if they choose to do so, see 45 C.F.R. 164.506(b); it reflects no preference in favor of use or disclosure; and it manifests no intent that private health information should be shared with federal personnel.[2]

b. Petitioners' extensive discussion of other cases finding state action in the absence of governmental compulsion (Pet. 13-21) is also largely beside the point. As the court of appeals recognized, the laws "struck down in these cases allowed private parties to take some action (usually discrimination based on race) where they would otherwise have been prohibited from doing so," Pet. App. 20a, and most of the cases concerned concrete

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[2] Despite the express provision in the Final Amended Rule allowing covered entities to seek consent for routine uses and disclosures, petitioners contend that the rule "provides significant *discouragement* to private entities that may wish to continue providing a consent process as they have in the past." Pet. 25. In support of that claim, petitioners characterize the consent process authorized by the Rule as "cumbersome," and they suggest that providers will be unwilling to enter into voluntary agreements restricting uses and disclosures because a failure to abide by such agreements "is a violation of the Rule subjecting the covered entity to potential civil sanctions." *Ibid.* The fact that uses and disclosures in violation of a confidentiality agreement are treated as violations of the Final Amended Rule, however, simply underscores the strength of the privacy protections in that Rule. In any event, nothing in the Rule prevents covered entities from seeking consent to disclosures on an ad hoc basis, or from declining to make disclosures for which consent has not been given, even in the absence of a formal agreement to that effect.

governmental involvement in such conduct through funding, enforcement of private conduct or other means. The Final Amended Rule, by contrast, "has not enhanced covered entities' power, under federal or state law, to use or disclose confidential health information without patients' consent," *id.* at 23a, and there is no further involvement by the federal government in the private conduct of covered entities.

Although this Court has frequently found state action when government officials encouraged or facilitated private racial discrimination, Congress's failure to prohibit particular discriminatory conduct, standing alone, is not a sufficient basis for attributing the discrimination to the federal government. For example, Title VII's prohibition on racial discrimination in private employment applies only to "a person engaged in an industry affecting commerce who has fifteen or more employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year." 42 U.S.C. 2000e(b) (definition of "employer"); see, *e.g.*, *Arbaugh* v. *Y&H Corp.*, 126 S. Ct. 1235, 1239 (2006). The exclusion from Title VII's coverage of firms with fewer than 15 employees could not reasonably be viewed as a basis for attributing to the federal government any acts of racial discrimination that such firms might commit. Similarly here, HHS's decision not to impose a categorical ban on unconsented uses or disclosures of private health information does not constitute the sort of affirmative encouragement that would justify treating such private disclosures as the actions of the federal government.

c. Petitioners contend that the court of appeals' ruling conflicts with decisions of the D.C. and Fourth Circuits holding that "state action can be evidenced by 'en-

couragement and support' from the federal government even if it does not compel the private choice." Pet. 27 (citing, inter alia, *Franz* v. *United States*, 707 F.2d 582 (D.C. Cir. 1983), and *Doe* v. *Charleston Area Med. Ctr., Inc.*, 529 F.2d 638 (4th Cir. 1975)). But the court of appeals recognized that governmental encouragement and support of private conduct may, in some circumstances, justify treating that conduct as state action. See, *e.g.*, Pet. App. 20a-23a. The court simply held that HHS's decision not to require covered entities to obtain patient consent before using or disclosing protected health information for routine purposes does not represent the sort of affirmative encouragement that could make the use or disclosure of such information legally attributable to the government.[3]

Contrary to petitioners' contention (Pet. 28), the court of appeals did not base its decision on a "radical new formulation of the state action doctrine." Rather, after careful consideration of a variety of factors, the court of appeals concluded that the private conduct that is the anticipated source of harm to petitioners is not properly attributed to the federal government because the Final Amended Rule did not compel any non-consensual uses or disclosures of protected health information

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[3] Petitioners also criticize the court of appeals for not addressing the question whether HHS directly violated petitioners' privacy rights in its role "as a 'covered entity' charged with administration of the Medicare, Medicaid and Indian Health Services programs." Pet. 15 n.6. That claim lacks merit. The court of appeals correctly held that petitioners "did not challenge any use or disclosure [of information] by the Secretary himself, or urge that the third parties were somehow acting on the Secretary's behalf." Pet. App. 14a. Although petitioners suggest that general allegations in their complaint should be deemed sufficient to state such a claim, Pet. 15 n.6, they do not identify any specific allegations regarding HHS in its role as a covered entity.

and did not "enhance" covered entities' authority to take measures that were previously unlawful. Pet. App. 23a. The court's holding is correct and is consonant with the general principle that "permission of a private choice cannot support a finding of state action." *American Mfrs.*, 526 U.S. at 54.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

PAUL D. CLEMENT
Solicitor General

PETER D. KEISLER
Assistant Attorney General

MARK B. STERN
CHARLES W. SCARBOROUGH
Attorneys

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No. 05-1311

In the Supreme Court of the United States

CITIZENS FOR HEALTH; AMERICAN ASSOCIATION FOR HEALTH FREEDOM; AMERICAN ASSOCIATION OF PRACTICING PSYCHIATRISTS; AMERICAN MENTAL HEALTH ALLIANCE-USA; AMERICAN PSYCHOANALYTIC ASSOCIATION; NATIONAL COALITION OF MENTAL HEALTH PROFESSIONALS AND CONSUMERS; NEW HAMPSHIRE CITIZENS FOR HEALTH FREEDOM; SALLY SCOFIELD; TED KOREN, DC; MICHAELE DUNLAP, PSY.D.; MORTON ZIVAN, PH.D.; CALIFORNIA CONSUMER HEALTHCARE COUNCIL; CONGRESS OF CALIFORNIA SENIORS; HEALTH ADMINISTRATION RESPONSIBILITY PROJECT; DANIEL S. SHRAGER; EUGENE B. MEYER; JANE DOE; JANIS CHESTER; DEBORAH PEEL,
PETITIONERS

v.

MICHAEL O. LEAVITT, SECRETARY U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF

JAMES C. PYLES
Counsel of Record
Powers, Pyles, Sutter & Verville, P.C.
1875 Eye St., N.W.
Washington, D. C. 20006
202-466-6550

CURRY & TAYLOR ♦ WASH D.C. ♦ (202) 223-3160 ♦ USSCINFO.COM

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Reply Brief of Petitioners

As permitted by Rule 15.6 of the Rules of the Supreme Court, Petitioners ("Citizens") submit this reply brief to address new points raised by the Respondent in his brief in opposition to Petitioners' petition for certiorari.

In his opposition brief, Respondent relies extensively on the Court's ruling in American Mfrs. Mut. Ins. Co. v. Sullivan, 526 U.S. 40 (1999) and to a lesser extent on the holding in Arbaugh v. Y&H Corp., 126 S. Ct. 1235 (2006). Resp. Br. 9-11, 13. Neither party has cited these cases in the course of this litigation, nor did the Court of Appeals cite them or rely on their holdings in any way. The decision in Arbaugh involved whether an employee-numerosity requirement in the Civil Rights Act of 1964 was a jurisdictional requirement or an element of a plaintiff's claim for relief. 126 S. Ct. at 1242. The decision did not address the state action issue or the constitutional right to privacy, and is, therefore, irrelevant to the issues presented by Citizens.

Respondent seeks to make the decision in American Manufacturers relevant by mischaracterizing both the Amended Privacy Rule and the essence of Citizens' constitutional claim. Throughout his brief, Respondent describes the Amended Rule as merely allowing covered entities to seek consent and imposing restrictions on their ability to disclose Citizens' health information. Resp. Br. 4, 8. Respondent describes Citizens' complaint as contending that the rule violates their rights under the First and Fifth Amendments by failing to require certain health providers to obtain consent for the disclosure of their identifiable health information for purposes such as treatment and payment. Resp. Br. 8. See also Respondent's characterization of the issue as constitutionality of a regulation that does not require treatment providers to obtain consent (Resp. Br. (I)), "[p]etitioners believe that additional use and disclosure restrictions are warranted" (Resp. Br. 9), Amended Rule

described as "HHS' decision not to prohibit certain private disclosures" (Id.), Amended Rule "challenged principally on substantive due process grounds rather than Fourth Amendment grounds" (Resp. Br. 12), Amended Rule described as "HHS' decision not to impose a categorical ban on unconsented uses or disclosures of privacy information" (Resp. Br. 13).

Respondent carefully and repeatedly suppresses the fact that the Amended Rule not only eliminated the requirement in the Final Original Rule that health care providers obtain consent before disclosing individuals' identifiable health information but also granted "regulatory permission" to all covered entities, including the Secretary himself, and their business associates to use and disclose Citizens' identifiable health information for treatment, payment and health care operations without their consent and over their objection. Pet. 8a. Respondent also ignores the fact that this express federal authorization to violate Citizens' health information privacy was conferred by the Amended Rule on both private entities and federal officials for the first time in the nation's history. Pet. 2-4. See also Pet. 8a. Respondent's repeated suppression of this feature of the Amended Rule eloquently illustrates his appreciation of its significance with respect to the state action question.

Contrary to Respondent's description, Citizen's constitutional complaint is that federal "regulatory permission" for the disclosure of their identifiable health information by private and governmental entities granted by the Amended Rule has essentially eliminated their right to health information privacy as protected by the First, Fourth, Fifth and Ninth Amendments. Pet. 5. Both the District Court and the Court of Appeals found that Citizens' health information privacy was, in fact, being violated by covered entities because of the Amended Rule or imminently would be. Pet. 6, 8.

Like the Court of Appeals, Respondent cites no case law authority from this or any other court for the central

holding in the decision that state action cannot exist "unless the law itself suddenly authorized something that was previously prohibited." Pet. 9. Surely if there was a federal court decision at any level supporting this novel concept it would have been cited by the Court of Appeals or the Respondent. Respondent simply dismisses nearly 100 years of state action case law to the contrary as "largely beside the point." Resp. Br. 12.

By relying on the holding in American Manufacturers, Respondent concedes that the Court of Appeals in this case failed to apply the criteria that are essential for determining the existence of state action. The Court in that case, unlike the Court of Appeals here, examined whether the State provided "significant encouragement, either overt or covert" as well as whether it exercised coercive power in violating Citizens' health privacy. Compare Pet. 13-21 with Resp. Br. 10.[1] Further, Respondent, again like the Court of Appeals, fails even to mention this Court's recent holding in Brentwood Academy v. Tennessee Secondary School Ass'n, 531 U.S. 288, 121 S. Ct. 924 (2001) and the Court's recognition of the "judicial obligation" to assure that constitutional standards are invoked by examining a constitutional claim under established state action criteria. Pet. 21-28.

As the Brentwood Court noted, the determination of state action is a "necessarily fact-bound inquiry." 531 U.S. at 298, 121 S. Ct. at 932. Accordingly, the fact that the Amended Rule "replaced" the individual's right of consent for disclosure of health information with an unprecedented, explicit federal right for covered entities to disclose such health information is critical for determining whether state action is present.

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[1] The Court also considered a series of other state action criteria precisely as the Court of Appeals in this case failed to do. 526 U.S. at 55-58. See Pet. 21.

The issue in American Manufacturers was whether a private insurer's decision to withhold payment of workers' compensation claims for thirty days in order to assess the validity of the claims amounted to state action since the private action was based on an amendment to the state's workers' compensation statute. Prior to the amendment, the statute required all claims to be paid within 30 days without such an evaluation. 526 U.S. at 51. The Court found that, while "significant encouragement" of private action is a potential basis for a finding of state action, the encouragement in this case was too "subtle." 526 U.S. at 53.

The Court noted that it had never held that "the mere availability of a remedy for wrongful conduct" so significantly encourages private conduct as to make the State responsible for it. Id. The Court explained further that the amendment to the statute on which the private action was based merely "restored to insurers the narrow option, historically exercised by employers before the adoption of [the state's] workers' compensation law, to defer payment of a bill until it is substantiated." 526 U.S. at 54. Therefore, the effect of the amendment was as though the state had not acted, and State "inaction" typically cannot be viewed as "authorization" or "encouragement." Id.[2]

The Amended Privacy Rule in this case does not make available a remedy for wrongful conduct. To the contrary, the undisputed facts are that the Amended Rule authorized the disclosure of identifiable health information that is prohibited by many state laws and standards of

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[2] Respondent tries to stretch the holding in American Manufacturers—that "permission of a private choice cannot support a finding of state action"—into a "general principle." Resp. Br. 15. However, Respondent omits a critical word from the Court's holding which actually reads, "Such permission of a private choice cannot support a finding of state action." (emphasis added) 526 U.S. at 54. Thus, the holding cited by Respondent pertains specifically to situations where the State is merely removing an impediment to a preexisting right, a fact pattern not present in this case.

medical ethics. Citizens showed that they were prevented from asserting their privacy rights under state law because the Amended Rule authorized the disclosure of their health information without notice of the disclosure or notice of the recipient of the information. The Court of Appeals found this fact "regrettable and disquieting." Pet. 23a. Thus, the Amended Rule actually eliminates a privacy remedy that Citizens have historically enjoyed and is authorizing conduct that is wrongful under state laws and standards of medical ethics.

Nor does the Amended Rule restore a right to disclose Citizens' identifiable health information which covered entities or the Secretary once enjoyed. Rather the Amended Rule creates a wholly new and unprecedented right for covered entities, including the Secretary, to disclose Citizens' identifiable health information without their consent and over their objection. As both the District Court and the Court of Appeals noted, the undisputed facts show that prior to the Amended Rule, Citizens could control the disclosure of their health information, and after the adoption of the Amended Rule they could not. This loss of health information privacy was directly attributable to covered entities cloaking themselves in the mantle of federal authority conferred by the Rule. The Amended Rule unquestionably "changed the landscape" with respect to whether Citizens could protect the privacy of their health information. Pet. 35a, 63a-64a. The record also shows that, prior to the Amended Rule, "all hospitals" and "90 percent of the non-hospital providers" obtained consent for the disclosure of identifiable health information. 65 Fed. Reg. 82462 at 82,474, 82,771 (December 28, 2000).

Of course, unlike the State in American Manufacturers, the Secretary here actually conferred authority to violate Citizens' health privacy upon himself as a covered entity. The Court of Appeals did not find this fact relevant to whether Citizens' constitutional claims should be considered for the stated reason that Citizens did not

challenge any specific disclosures by HHS or any of the federal agency health plans it supervises. Pet. 38a. The Court of Appeals thereby ignored the principle recognized by this Court in Santa Fe Indep. School District v. Doe, 530 U.S. 290, 316, 120 S. Ct. 2266, 2282-83 (2000) that the simple enactment or adoption of a measure by a State that is intended to authorize private individuals to violate constitutionally protected rights is a sufficient basis for constitutional review and relief even if the authority is not exercised.

Further, Respondent has never disputed that the Secretary can disclose, and is disclosing, Citizens' identifiable health information under the self-conferred authority of the Amended Rule. In fact, the Secretary has placed notices to this effect on a public website.[3]

Respondent erroneously argues that the facts in American Manufacturers are more analogous to this case than those in Skinner v. Railway Labor Executives, 489 U.S. 602, 109 S. Ct. 1402 (1989) cited by Petitioners. Resp. Br. 11-12 and Pet. 20-21. The issue in Skinner was whether a regulation issued by a federal agency that authorized, but did not require, private railroads to infringe the medical privacy of their employees violated the employees' right to health privacy protected by the Fourth Amendment. 489 U.S. at 606.

The Secretary of Transportation, who had issued the regulation in Skinner, made exactly the argument that was the basis for the Court of Appeal's decision in this case—that there was no state action solely because the regulation was permissive and did not compel private entities to take any action. 489 U.S. at 614. The Court expressly rejected that

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[3] See http://www.medicare.gov/privacypractices.asp, "Medicare **has the right** to give out your personal medical information [for routine uses]." (emphasis original). Indian Health Serv., Notice of Privacy Practices, (2003) "We will use and disclose your health information for [routine uses]."

argument and found state action based on "clear indices of the Government's encouragement, endorsement, and participation" in the private action. 489 U.S. at 615-616. Respondent argues that those indices are not present in this case. Resp. Br. 12. However, the Court of Appeals' decision is devoid of any such analysis, and Respondent cannot supply a rationale that is absent from the court's decision.

In any event, there are much stronger indices of government involvement in the violation of Citizens' rights to heath privacy than were present in Skinner. The regulation at issue in Skinner provided that breath and urine tests "may" be ordered by railroads under certain circumstances without a warrant and without a particularized suspicion of drug or alcohol use. 489 U.S. at 611. The specific question before the Court was whether this permissive violation of individuals' health privacy violated their right to privacy protected by the Fourth Amendment. The Court found state action was present because, among other reasons, the agency had expressed "its desire to share the fruits of such intrusions." 489 U.S. at 615. Respondent in this case is far more involved because he has granted authority to himself to directly violate the health information privacy of Citizens.

Another reason for the Skinner Court's finding of state action was that the government had "removed all legal barriers" to the violation of the employees' health privacy. Id. Likewise, the Amended Rule has authorized covered entities to violate Citizens' health privacy without notice or an opportunity to assert their privacy rights under state law or the Constitution.

The Skinner Court also relied on the fact that the railroad could not divest itself or otherwise compromise the authority conferred by the regulation. Id. Similarly, the Amended Rule confers discretion on covered entities to provide a consent process by agreeing to requests for restrictions on the disclosure of health information. However, the Rule reserves the authority to covered entities to deny those requests, and they cannot divest themselves of

that authority. 45 C.F.R. §164.522(a)(1)(B)(ii) (2002). It was an undisputed finding by the District Court that all such requests have been summarily denied based on the authority granted to covered entities in the Rule. Pet. 63a.

The Court also found it persuasive that the federal agency had "made plain" its strong preference for the testing. 489 U.S. at 615. Similarly the Amended Rule expresses a strong preference for unauthorized disclosure of Citizens' health information by compelling all covered entities to provide a notice of privacy practices that must first describe the nonconsensual disclosures authorized by the Rule regardless of the privacy practices actually adopted by the covered entity. That preference resulted in the near universal adoption of the Rule's nonconsensual disclosure process for identifiable health information. Pet. 24.

Perhaps most significantly, the Skinner Court's state action finding also rested on the fact that the employees were not free to decline the employer's request that they submit to the breath or urine tests. 489 U.S. at 615. As the District Court and Court of Appeals both acknowledged, Citizens have no option under the Amended Rule to refuse to have their identifiable health information disclosed by covered entities. Pet. 34a-36a, 61a-65a.

At least one factual difference between Skinner and the present case even more strongly supports a finding of state action. The regulation in Skinner involved only breath and urine tests under specific circumstances, while the Amended Rule infringes the right to privacy for all health information in broadly defined routine situations. The factual situation in this case is more analogous to Skinner than to American Manufacturers in that the right conferred on railroad employers to administer the breath and urine tests, like the right of covered entities to disclose Citizens' health information, was unprecedented.

Finally, Respondent argues that the Amended Rule does not violate any of Citizens existing privacy protections. Resp. Br. 8. As the Court in Skinner found, however,

individuals have a constitutionally protected right to privacy where they have "an expectation of privacy that society is prepared to recognize as reasonable." 489 U.S. at 616. Whether that right will be upheld in a particular case may depend upon whether the individuals participate in an industry that is regulated pervasively to ensure safety. 489 U.S. at 627.[4] In this case, Citizens have shown that they have an expectation of privacy for their identifiable health information that society has always recognized as reasonable as evidenced by established standards of medical ethics and established medical practice. Constitutional protection for this right has been recognized repeatedly. See, e.g., Ferguson v. City of Charleston, 532 U.S. 67, 78, 121 S. Ct. 1281, 1288 (2001); Whalen v. Roe, 429 U.S. 589, 97 S. Ct. 869 (1977); United States v. Scott, 424 F.3d 888 (9th Cir. 2005); Douglas v. Dobbs, 419 F.3d 1097 (10th Cir. 2005); Tucson Woman's Clinic v. Eden, 371 F.3d 1173 (4th Cir. 2004). The Court of Appeals may be correct that "the scope of the constitutional right to privacy in one's medical information is largely unresolved," but there can be no doubt that Citizens have such a right. The Amended Rule authorizes the disclosure of Citizens' past, present and future health information regardless of whether they seek health services or file a claim for reimbursement. Citizens have done nothing to diminish that reasonable expectation of privacy, and they have a constitutionally protected right to not have that right violated by the federal government either directly or by authorizing others to extinguish it indirectly.

Respondent has shown no reason why this petition should not be granted.

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[4] In Skinner, the Court ultimately upheld the constitutionality of the testing regulation largely because of the diminished expectation of privacy by railroad employees performing duties that could risk public safety. Petitioners inadvertently stated that this rule had been struck down on constitutional grounds. Pet. 20.

Respectfully submitted,

James C. Pyles
Counsel of Record
Powers, Pyles, Sutter & Verville, P.C.
1875 Eye St., N.W.
Washington, D.C. 20006
202-466-6550

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IN THE

Supreme Court of the United States

CITIZENS FOR HEALTH, *et al.*,

Petitioners,

v.

MICHAEL O. LEAVITT,
Secretary of Health and Human Services,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRIEF OF *AMICI CURIAE* CONSUMER ATTORNEYS OF CALIFORNIA, FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS, CONGRESS OF CALIFORNIA SENIORS, CALIFORNIA CONSUMER FEDERATION, AND HEALTH ADMINISTRATION RESPONSIBILITY PROJECT IN SUPPORT OF PETITIONERS

SHARON J. ARKIN
ARKIN & GLOVSKY
27031 Vista Terrace
Suite 201
Lake Forest, CA 92630
(949) 455-9300

Attorneys for Amici Curiae

201724

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

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STATEMENT OF INTEREST OF *AMICI* [1]

Consumer Attorneys of California ("Consumer Attorneys") is a voluntary membership organization representing approximately 6,000 associated attorneys practicing throughout California. The organization was founded in 1962. Its membership consists primarily of attorneys who represent individuals subjected in a variety of ways to personal injury, employment discrimination, and other harmful business and governmental practices. Consumer Attorneys has taken a leading role in advancing and protecting the rights of injured consumers in both the courts and the Legislature.

Foundation for Taxpayer and Consumer Rights (FTCR) is a nationally recognized, California-based nonprofit, nonpartisan consumer watchdog organization that specializes in insurance and health care reform. Founded in 1985, FTCR advocates for the rights of patients, ratepayers, and policyholders and seeks to make corporations accountable in court. FTCR has a strong interest in upholding the privacy protections of California consumers, particularly their right to medical privacy.

Congress of California Seniors (CCS) is a statewide non-profit education and advocacy organization dedicated to improving the life of seniors and their families. CCS

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1. This brief has been authored in its entirety by undersigned counsel for the *amici curiae*. No person or entity, other than the named *amici* and their counsel, made any monetary contribution to the preparation and submission of this brief. The parties have consented to the filing of this brief and their letters of consent are being lodged herewith.

devotes its efforts to legislative and consumer affairs that deal primarily with issues concerning older adults. CCS conducts research, analyzes issues and provides voter and consumer education to its members. Through an effective legislative committee, CCS initiates and monitors legislation, testifies at hearings and takes appropriate grass-roots action on pending and proposed legislation. When necessary, CCS initiates or joins in lawsuits to protect consumers. CCS's constituents will be seriously impacted by the decision here and is therefore vitally interested in the issues presented here.

California Consumer Federation (CCF) is non-profit consumer advocacy organization, established in 1960, for the purpose of enacting consumer protection laws and regulations, ensuring their enforcement and conducting education and research on consumer matters. CFC has filed amicus briefs in both state and federal courts in matters, such as this one, that relate to the protection of consumers. CFC has extensive experience relating to the problems faced by consumers when they are subjected to invasion of their medical privacy.

Health Administration Responsibility Project (HARP) is a non-profit organization that serves as an educational and informational resource for patients, doctors, and attorneys regarding managed care organizations, and seeks to enhance the quality of medical care benefits provided in the managed care setting. Because this case implicates medical privacy issues, HARP has an immediate interest in assuring that medical privacy protections remain viable and enforceable.

The issue in this case is one of grave importance to consumers. As discussed below, maintaining the privacy of their medical information is universally an issue that consumers care very deeply about. Because the Amended Rule significantly impacts the right to medical privacy, it is an issue which the *amici* believe they have a responsibility to address with this Court. Additionally, the response of the medical industry in California has been to apply the Amended Rule as though it had preemptive effect and has resulted in significant breaches of California's own privacy statutes. Accordingly, the *amici* have a vital interest in protecting California consumers from unwarranted and illegal violations of their medical privacy which result from the inappropriateness of the Amended Rule.

Counsel for the *amici* is familiar with the issues and the arguments presented by the parties whom this brief is submitted in support of and this brief is intended to emphasize the public policy considerations underlying the legal analysis presented by the Appellants.

LEGAL ARGUMENT

I. Certiorari Should Be Granted Because, As A Matter Of Public Policy, Constitutionality And State Law Concerns, Medical Privacy Is An Issue Of Overwhelming Importance And The Court Of Appeals Decision Opens The Door To Massive Invasion Of The Public's Constitutional Right To Privacy Of Their Medical Affairs

The right to privacy, generally, is not only an issue of constitutional magnitude, it is an issue of overwhelming importance to the vast majority of Americans. A 1999 Gallup poll found that 78% of Americans "feel it is very important that their medical records be kept confidential." (Institute for Health Freedom, *Public Attitudes Toward Medical* Privacy, The Gallup Organization, September 2000, available at *http://forhealthfreedom.org/Gallupsurvey/IHF-Gallup.html*, accessed June 9, 2006.) Even after receiving a flurry of HIPPA privacy notices from medical providers, 67% of Americans are still concerned about privacy of their medical records and 13% have actually put their health at risk in order to avoid disclosure of private medical information. (National Consumer Health Privacy Survey, 2005, California HealthCare Foundation, Forrester Research, Inc., available at *http://www.chcf.org/topics/view.cfm ?itemID=115694*, accessed June 9, 2006.)

And this concern is echoed in the decisions of this Court, in state constitutional amendments and in statutes passed by Congress itself:

- This Court recently reiterated the importance and fundamental nature of the right to privacy in striking down

the Texas anti-sodomy law. (*Lawrence v. Texas*, 539 U.S. 558, 123 S. Ct. 2472, 156 L. Ed. 2d 508 (2003).)

- California's constitution was amended to confirm privacy as a fundamental right. (Cal. Const., Article 1, section 1.)

- Congress passed the Gramm-Leach-Bliley Act in order to specifically protect citizens' financial privacy. (*See* 15 U.S.C. sections 6801, *et seq.*)

The importance of the right to privacy was recognized over a century ago — even before the advent of the "Information Age" and the Internet. In 1890, Louis Brandeis and Samuel Warren acknowledged in their Harvard Law Review article that "[o]f the desirability — indeed of the necessity — of some protection [of privacy], there can, it is believed, be no doubt." (Warren & Brandeis, 4 Harv. Law. R., No. 5, December 15, 1890.)

One of the most compelling discussions of the importance of medical privacy was made by the prior administration's Secretary in enacting the Original Rule. (*See* 65 Fed. Reg. 82,462.) The Secretary first recognized that "[p]rivacy is ***a fundamental right.***" (*Id.*, at 82,464; emphasis added.)

More specifically with respect to the goals and purposes of HIPPA, the Secretary acknowledged that the purpose of the regulations authorized by Congress under HIPPA was to "establish[ ] standards and ***protections*** for health information systems." (*Id.*, at 82, 463; emphasis added.) Further, the Secretary declared that "[i]n enacting HIPPA, Congress recognized the fact that ***administrative simplification cannot succeed if we do not also protect the privacy and confidentiality of personal health information.***" (*Id.*; emphasis added.)

Finally, the Secretary concluded that, because of the high level of public concern about the confidentiality of medical records, privacy protections are essential "for the effective delivery of health care, both to individuals and populations" and "is a ***necessary foundation*** for delivery of high quality health care." (*Id.*, at 82,467.) Most compellingly, the Secretary noted:

> In short, ***the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers***. The need for privacy of health information, in particular, has long been recognized as ***critical*** to the delivery of needed medical care. More than anything else, the relationship between a patient and a clinician is based on trust.
>
> * * *
>
> Individuals cannot be expected to share the most intimate details of their lives ***unless they have confidence that such information will not be used or shared inappropriately***. Privacy violations reduce consumers' trust in the health care system and institutions that serve them. Such a loss of faith can impede the quality of the health care they receive, and can harm the financial health of health care institutions. (*Id.*, emphasis added).

The Secretary's analysis in this regard emphasizes that the protection of medical privacy is the foundation upon which efficiencies in the delivery of health care must be built. In other words, it is not a situation where a balancing can

take place, *i.e.*, where privacy protections can be abrogated in order to enhance the efficient delivery of health care. This is a situation where, as the Secretary originally acknowledged, efficient delivery of health care cannot be achieved in the first instance ***unless*** adequate privacy protections are in place ***first***.

This is a reality: Efficient and effective medical care cannot be achieved in the absence of privacy protections. As explained in the National Consumer Health Privacy Survey, 2005, sponsored by the California Healthcare Foundation, 13% of consumers "put their health at risk by engaging in such behaviors as: avoiding their regular doctor, asking their doctor to fudge a diagnosis, paying for a test because they didn't want to submit a claim, or avoiding a test altogether" because of privacy concerns.

The Original Rule, in fact, accomplished the goal of providing efficient medical care without unwarranted invasion of the right to privacy. It established the minimum protections necessary for patient privacy, thereby enhancing the efficient delivery of medical care at the micro level, i.e., between the patient and the health care provider. The Original Rule then built upon that foundation a process for maximizing the efficiency of health care communications and interactions, ***while maintaining the foundational privacy protections***.

The Court of Appeals based its constitutional analysis on the precept that the HIPPA regulation is merely "voluntary," *i.e.*, that "covered entities" ***can*** agree to protect patients' privacy — if they want. (*Citizens for Health v. Leavitt*, 428 F.3d 167, 179-80 (3d Cir. 2005).) The practical reality that the Court of Appeals refused to face is that they simply don't want to. And they won't. Business and industry

— whether the healthcare industry or otherwise — survive on marketing and information. They want that information and they are voracious collectors of it. They will not "voluntarily" limit what they have access to. And a recent article in *Consumer Reports* provides a graphic example. As the March 2006 article notes, psychotherapy notes "may be given to an insurer's employees for "training purposes." One plastic surgeon's notice tells his patients that he "may use or disclose your demographic information and the dates that you received treatment from us in order to contact you for fund-raising activities supported by our office." (*Consumer Reports*, The new threat to your medical privacy, March 2006 Available at *http://www.consumerreports.org/ cro/health-fitness/health-care/electronic-medical-records 06/overview /index.htm*, accessed June 9, 2006.)

The Court of Appeals's attitude of unconcern about the practical effects on the average American of the disclosures that will occur as the result of the Amended Rule is insupportable. Review by this Court is imperative so that the congressional goals of HIPPA can be effectuated.

CONCLUSION

The right of medical privacy is of paramount importance to consumers. (65 Fed. Reg. 82,462, at 82,465; Institute for Health Freedom, *Public Attitudes Toward Medical* Privacy, The Gallup Organization, September 2000, available at *http://forhealthfreedom.org/Gallupsurvey/IHF-Gallup.html*, accessed June 9, 2006; National Consumer Health Privacy Survey, 2005, California HealthCare Foundation, Forrester Research, Inc., available at *http://www.chcf.org/topics/view. cfm ?itemID= 115694*, accessed June 9, 2006.) They, in fact, believe privacy is more important than the actual receipt of medical care itself, as evidenced by the fact that they would rather withdraw from the medical care system than risk privacy violations. (*Id.*, at 82, 468; National Consumer Health Privacy Survey, 2005, California HealthCare Foundation, Forrester Research, Inc., available at *http://www.chcf.org/topics/view. cfm ?itemID= 115694*, accessed June 9, 2006.) This, then, requires that the efficiencies in the delivery of health care be predicated on a sound foundation for protection of patient privacy rights. The Amended Rule fails to accomplish this goal and, in doing so, undermines congressional intent in enacting and implementing HIPPA. That being the case, review by this Court is essential in order to assure that congressional intent is enforced and the privacy protections needed and wanted by the American people are effectuated.

Respectfully submitted,

SHARON J. ARKIN
ARKIN & GLOVSKY
27031 Vista Terrace
Suite 201
Lake Forest, CA 92630
(949) 455-9300

Attorneys for Amici Curiae

(2)

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IN THE

Supreme Court of the United States

CITIZENS FOR HEALTH, *et al.*,
Petitioners,

v.

MICHAEL O. LEAVITT, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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BRIEF OF LEONARD MORSE, M.D., GUENTER L. SPANKNEBEL, M.D., WAYNE B. GLAZIER, M.D., GRAHAM L. SPRUIELL, M.D., AND ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

DAVID P. FELSHER
Counsel of Record
488 Madison Avenue
New York, NY 10022
(212) 308-8505

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QUESTIONS PRESENTED

1. May a lower federal court ignore Supreme Court precedent and invent its own "State Action Doctrine"?

2. If not:

   a. May Congress add to the requirements of the Presentment Clause by legislatively restricting its own time to pass a law?

   b. May an agency or executive department set its own boundaries of congressionally delegated authority?

   c. Does the Constitution authorize the federal government to impair the obligations of physician-patient contracts?

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INTERESTS OF *AMICI CURIAE* [1, 2]

Amicus Leonard Morse, M.D., specializes in internal medicine-infectious diseases. He is a past-Chair of the American Medical Association's Council on Ethical and Judicial

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[1] In compliance with Supreme Court Rule 37.6, this brief was not written in whole or in part by counsel for a party, and no person or entity other than *Amici Curiae* and their counsel has made any monetary contribution to the brief's preparation and submission. The parties consent to the filing of this brief.

[2] Medical records of the members of this Court and their staffs may be at risk to the extent that each individual participates in the "Federal Employees Health Benefits Program. . . ." *See* 42 U.S.C.§1320d(5)(M); 45 C.F.R. §160.103.

Affairs and a past-President of Massachusetts Medical Society ("MMS") and of Boston Medical Library. Dr. Morse is Professor of Clinical Medicine at University of Massachusetts Medical School and Commissioner of Public Health for Worcester, Massachusetts.

Amicus Guenter L. Spanknebel, M.D., privately practices gastroenterology and is also past-President of MMS. He is currently Chair of the History Committee and Vice-Chair of the Judicial Committee of MMS. He is Associate Professor of Medicine at University of Massachusetts Medical School and is Assistant Dean for Continuing Medical Education at University of Massachusetts Medical Center-Memorial Campus. He is also on the faculty of Tufts Medical School and is a Trustee of the Health Foundation of Central Massachusetts.

Amicus Wayne B. Glazier, M.D., privately practices urology. He is Chairman of the Health Foundation of Central Massachusetts and President of the Massachusetts Independent Physicians' Association.

Amicus Graham Spruiell, M.D., privately practices psychiatry and psychoanalysis in Boston and is the Chair of the Faculty at the Psychoanalytic Institute of New England, East, Inc.[3]

Amicus Association of American Physicians and Surgeons, Inc. ("AAPS") is a nationwide non-partisan professional association of thousands of physicians in all types of practices and specialties. Since it was founded in 1943, AAPS has been dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the sanctity of the patient-physician relationship.

Pursuant to § 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. No. 104-

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[3] Doctors Morse, Spanknebel, Glazier and Spruiell submit this brief as individual providers and patients and not on behalf of any other entity.

191, 110 Stat. 1936 *et seq.* (August 21, 1996), the Secretary of the United States Department of Health and Human Services ("HHS") issued health privacy regulations ("Regulations").[4] *Amici* believe the Regulations compromise the trust inherent in the patient-physician relationship and reduce patient candor resulting in increased diagnostic and treatment risks. Under the Regulations, the locus of decision-making regarding access to patient medical records is shifted from the patient to physicians and other covered entities and their business associates.

By eliminating patient consent and authorization for the use and disclosure of patient medical information in most situations, the Regulations ignore principles attributed to Hippocrates more than 2,400 years ago and obliterate the foundation of the medical profession—trust between a patient and his or her physician.

As providers and patients, *Amici* disagree with the substance of the Regulations.[5] However, as *amici curiae*, they

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[4] On November 3, 1999, HHS published proposed health privacy regulations. 64 Fed. Reg. 59918 *et seq.* After an extended comment period, the final health privacy regulations were issued in December 2000 ("Original Regulations"). 65 Fed. Reg. 82462 *et seq.* (December 28, 2000), and became effective on April 14, 2001, 66 Fed. Reg. 12434 (February 26, 2001). Modified health privacy regulations were proposed on March 27, 2002, 67 Fed. Reg. 14776 *et seq.*, and were finalized on August 14, 2002, 67 Fed. Reg. 53182 *et seq.* ("Modified Regulations").

[5] *Amici* consider themselves fiduciaries with respect to patient confidences. They believe the Regulations encourage them as well as all covered entities and their business associates to breach that fiduciary duty. *Aufrichtig v. Lowell*, 85 N.Y.2d 540, 546 (1995) ("The physician-patient relationship thus operates and flourishes in an atmosphere of transcendent trust and confidence and is infused with fiduciary obligations.") (citation omitted). *See generally*, Austin Scott, *The Fiduciary Principle*, 37 Cal. L. Rev. 539 (1949); *Meinhard v. Salmon*, 249 N.Y.458, 464 (1928) (Cardozo, Ch. J.) (Fiduciaries are held to higher standards than others. "Not honesty alone, but the punctilio of an honor the most sensitive, is then the standard of behavior").

direct the Court's attention to the Third Circuit's misapplication of the "State Action Doctrine" and to important constitutional issues that will not be addressed unless that error is corrected. These issues question the power and process by which Congress attempted to authorize the Secretary to issue the Regulations.

Today, patient records may be transmitted worldwide in an instant, often without patient knowledge or consent. An inadvertent or intentional release of patient information could endanger millions of patient records at a time. *See*, "VA: Data on 26.5M veterans stolen", USA Today, May 23, 2006, at A1, col. 4; *see also.*, "Bank Loses Tapes of Records of 1.2 Million With Visa Cards", N.Y.Times, Feb. 26, 2005, at A9, col. 3 (Personal information of about 1.2 million federal employees, including United States Senators, was lost by Bank of America); *see also* 65 Fed. Reg. at 82467. Coupling the rapidly evolving technological landscape with exceptions to the consent requirements for disclosures in connection with "treatment, payment and healthcare operations" creates a recipe for disaster. Once the records are released, it is often too difficult or impossible to reverse the breach of privacy.[6]

Although Congress after Congress attempted to strike a balance between public policy goals and the need to keep personal information private, Congress failed to enact any legislation regarding the disclosure of personal medical information because of the inherent tension between these competing objectives. In 1996, Congress decided to break that legislative deadlock, but did so using a blatantly unconstitutional vehicle, *i.e.* § 264(c)(1) of HIPAA. Through § 264(c)(1), Congress imposed, on itself, a three-year deadline to enact legislation governing medical privacy. Under that provision, Congress directed the Secretary to promulgate

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[6] This is analogous to letting air out of a balloon and then futilely attempting to refill that balloon with the same air molecules. It cannot be done.

medical privacy regulations if Congress failed to enact medical privacy legislation by the deadline. Congress missed that deadline and the Secretary ultimately promulgated the Regulations. By enacting § 264(c)(1), Congress sought to accomplish exactly what the Constitution's first clause does not allow: transferring to an executive department authority to enact legislation upon the failure of the legislative process in Congress. U.S. CONST. Art. 1, § 1 ("All legislative Powers herein granted shall be vested in a Congress of the United States. . . .").

Section 264(c)(1) is an effort to accomplish an unconstitutional end by an unconstitutional means. This section is a revolutionary attempt to spare Congress difficult decisions regarding medical privacy by allowing the Secretary to make decisions instead. It undermines, in fundamental and dangerous ways, the Constitution's mechanism for enacting federal laws. Section 264(c)(1) has taken legislative responsibility from Congress and delegated it to the Secretary. It is an impermissible effort by Congress to delegate to the Secretary its most basic duty—to determine what the law shall be. As such, it radically upsets the constitutionally contemplated process of political compromise within the legislative branch and between the legislative and executive branches. This Court must, in this case, protect Congress from itself, and thereby protect the Nation and its people.

ARGUMENT

I. THE COURT BELOW MISAPPLIED THE "STATE ACTION DOCTRINE" BECAUSE HHS IS A COVERED ENTITY

Although the Third Circuit concedes, "the promulgation of the Amended Rule by the Secretary—is clearly government conduct", Appendix to Petition ("App.") 14a, its "state action" analysis relies on the premise that some "third party actor" is not before the court. *Amici* disagree. As a covered entity, the Secretary is that "third party actor" and he is before

the Court. Furthermore, *Amici* believe the promulgation of the Regulations also establishes sufficient "state action" to allow this case to proceed.

The heart of the Third Circuit's "state action" analysis is contained in the text accompanying footnote 12:

> [T]he injury that Citizens allege is that their "personal health information" is being "*used and disclosed*, without their permission and against their will" *by third parties* . . . To support their claims, Citizens point to privacy notices that they received from private health care providers and pharmacies . . . *Citizens did not challenge any use or disclosure by the Secretary himself*, or urge that the third parties were somehow acting on the Secretary's behalf, before the District Court.

App. 14a (emphasis added)(citation omitted).

This analysis ignores allegation 71 of the Complaint. This allegation clearly refers to all covered entities and their business associates. The Secretary is clearly contemplated by the reference to "all covered entities". Allegation 71 provides:

> . . . Defendant has further violated Plaintiffs' rights under the Fifth Amendment by conferring express authorization and "regulatory permission" upon **ALL COVERED ENTITIES** and their business associates to use and disclose even the most sensitive of Plaintiffs' health information without their permission and against their will, retroactively and prospectively.

First Amended Complaint for Declaratory and Injunctive Relief: Constitutional Claim (emphasis added).

Medicare, Medicaid, and the Indian Health Services Programs are defined as "health plans" under the Administrative Simplification provisions of HIPAA. 42 U.S.C. § 1320d (5) (D, E, & L). *See also*, 45 C.F.R. §164.103. As "health plans", these programs are covered entities under 42 U.S.C. § 1320d-1. Based upon these definitions, this Court must conclude that the actor who caused plaintiffs' injuries, *i.e.* the

Secretary, as opposed to an unnamed third party actor, is before the Court.

Although the Third Circuit created the "third party actor" as a straw man in its "state action" analysis, it ignored the Defendant's role as that "third party actor."[7] As Secretary, Defendant supervises Medicare, Medicaid and Indian Health Services Programs, covered entities with 42.1 million, 44.7 million and 1.6 million enrollees, respectively. United States Department of Health and Human Services, What We Do, *available at* www.hhs.gov/about/whatwedo.html. This makes the Secretary the single largest covered entity, using and disclosing more individually identifiable health information ("IIHI") than anyone else.[8] Unlike a criminal defendant who argues that someone else committed the crime, the Secretary cannot say someone else "acted". He wears two hats in this case—as promulgator of the challenged regulations and as the ultimate "third party actor" *i.e.* covered entity. In either capacity, he is a governmental actor and the "State Action Doctrine" is satisfied.

II. THE SECRETARY LACKS AUTHORITY UNDER §264(C)(1) BECAUSE THAT SECTION VIOLATES THE CONSTITUTION

While the District Court examined the contentions of the parties regarding the scope of authority delegated to the

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[7] The Third Circuit apparently ignored its own findings with respect to justiciability, both with respect to the "injury in fact" and "traceability". The court said: "Citizens alleged injuries are 'fairly traceable' to the Secretary's promulgation of the Privacy Rule. . . ." App. 35a-36a.

[8] Given the extent to which the Secretary is a "third party actor" with respect to these programs, it is unnecessary to analyze the Secretary's role in other federally run health plans covering millions of additional enrollees. Such "health plans" include programs and care provided by the Department of Defense, the Veterans Administration, the Federal Employees Health Benefits Program, and the Civilian Health and Medical Program of the Uniformed Services. 42 U.S.C. § 1320d(5)(I, J, K & M).

Secretary, App. 71a-74a, the District Court neglected to address the validity of that delegation under § 264(c)(1). That should have been done first. The invalidity of § 264(c)(1) obviates any need for its construction. This Court has stated "a court may consider an issue "antecedent to . . . and ultimately dispositive of" the dispute before it, even an issue the parties fail to identify and brief." *U.S. National Bank of Oregon v. Independent Insurance Agents*, 508 U.S. 439, 447 (1993) ("USNB") (citations omitted).

Amici believe that § 264(c)(1) is unconstitutional and delegated no authority to the Secretary. By ignoring the validity of § 264(c)(1), the courts below have issued advisory opinions regarding regulations issued pursuant to a "non-existent" act of Congress. Section 264(c)(1) is unconstitutional because it (1) violates the Bicameral and Presentment Clauses; (2) violates the Non-Delegation Doctrine[9]; and (3) exceeds the powers granted to Congress under the Constitution. As discussed below, Congress never enacted legislation regarding the standards for privacy of individually identifiable health information. It merely directed the Secretary to make legislative recommendations. Congressional authority to issue the Regulations is, in fact, a null set.

It has been a long-standing principle of statutory construction that when a court is asked to construe a law, it has the authority to determine if that law exists.

> " . . . [A] court properly asked to construe a law has the constitutional power to determine whether the law exists,

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[9] Although the Secretary argued to both courts below that he received a broad delegation of authority from Congress to promulgate privacy standards, he contended it was inappropriate for the Third Circuit to address *Amici's* non-delegation argument. Brief for Appellee, 35n.8. In response to the Secretary's contention, *Amici* made a motion to file a reply brief pursuant to Fed. R. App. P. 29 (b&f) regarding the applicability of the Non-Delegation Doctrine. Motion of Guenter L. Spanknebel, M.D. [*et al.*], as *Amici Curiae*, to File Reply Brief. The Third Circuit granted the motion. Order, dated March 4, 2005).

> cf. *Cohens v. Virginia*, 6 Wheat. 264, 405 (1821) ("[I]f, in any controversy depending in a court, the cause should depend on the validity of such a law, that would be a case arising under the constitution, to which the judicial power of the United States would extend") (Marshall, C.J.). The contrary conclusion would permit litigants, by agreeing on the legal issue presented, to extract the opinion of a court on hypothetical Acts of Congress or dubious constitutional principles, an opinion that would be difficult to characterize as anything but advisory."

USNB, 508 U.S. at 446-447.

Under Supreme Court precedent, "[w]hen an issue or claim is properly before the court, the court is not limited to the particular legal theories advanced by the parties, but rather retains the independent power to identify and *apply the proper construction of governing law*." *Kamen v. Kemper Financial Services, Inc.*, 500 U.S. 90, 99 (1991) (emphasis added); *USNB* 508 U.S. at 446 (*quoting Kamen*). The failure of litigants to argue the legal issues correctly does not render an appellate court powerless to address those issues properly.

> "Appellate review does not consist of supine submission to erroneous legal concepts even though none of the parties declaimed the applicable law below. [An appellate court's] duty is to enunciate the law on the record facts. Neither the parties nor the trial judge, by agreement or passivity, can force us to abdicate our appellate responsibility."

Forshey v. Principi, 284 F.3d 1335, 1357 n.20 (Fed. Cir.), *cert. denied*, 537 U.S. 823 (2002) *quoting Empire Life Ins. Co. of Am. v. Valdak Corp.*, 468 F.2d 330, 334 (5th Cir. 1972). Indeed, appellate review of the proper law prevents misapplication of the law, injustice, and the construction of hypothetical laws.

A. Section 264(c)(1) Unconstitutionally Limits the Time of Congress to Pass a Law

Since our nation was founded, a "single, finely wrought and exhaustively considered, procedure" has been used to enact federal legislation. *Immigration and Naturalization Service v. Chadha*, 462 U.S. 919, 951 (1983). That procedure is specified in the Constitution's Bicameral and Presentment Clauses. Strict compliance with that procedure is required. When Congress delegates its lawmaking function to another branch or independent agency it may not legislatively alter the Presentment Clause. If it does, the delegation is unconstitutional. For example, the legislative veto and line item veto were declared unconstitutional. *Id.* at 959; *Clinton v. City of New York*, 524 U.S. 417 (1998) (Stevens,J.). Similarly, when Congress conditions the delegation of its lawmaking function upon the restriction of its own time to consider legislation, it alters that legislative procedure. Section 264(c)(1) contains such an alteration.

The Bicameral and Presentment Clauses require passage of exactly the same text by both Houses and presentment to the President. *Clinton*, 524 U.S. at 448. Those procedures may not be statutorily supplemented or modified. They may be altered only by a constitutional amendment. *Clinton*, 524 U.S. at 449; *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 837 (1995) (Stevens, J.); *Oregon v. Mitchell*, 400 U.S. 112, 128 (1970). Section 264(c)(1) alters the procedure without ratifying a constitutional amendment in accordance with Article V. Pursuant to § 264(c)(1), once three years had elapsed without passage of new health privacy legislation, the Secretary had six months to regulate (unless the House, Senate and the President had agreed otherwise). Furthermore, without § 264(c)(1), the Secretary may not regulate health privacy unless the House, Senate and President agree on health privacy legislation.

A law such as §264(c)(1), which completely delegates legislative responsibility to an executive department or independent agency, violates the Constitution's letter and spirit. The abdication of congressional responsibility encouraged by § 264(c)(1) is philosophically at odds with the Constitution. *Clinton*, 524 U.S. at 452 (Kennedy, J., concurring) ("Abdication of responsibility is not part of the constitutional design"). Section 264(c)(1) turned delegation on its head and conditioned rulemaking authority solely upon the failure of Congress to take action between two specified dates. It allowed Congress to avoid tough decisions. As a result, the scope of delegation was set by the Secretary rather than by agreement of both Houses and the President.

Although not every action taken by Congress is subject to the bicameralism and presentment requirements, those requirements must be met when Congress exercises legislative power. Whether particular actions are an "exercise of legislative power depends not on their form but upon 'whether they contain matter which is properly to be regarded as legislative in its character and effect.'" *Chadha*, 462 U.S. at 952 (citation omitted).

The legislative character of an action may be established by an examination of the congressional action that it supplants. This "Supplantation Principle" was used to analyze the constitutionality of the legislative veto in *Chadha*. *Id.* at 952 ("The legislative character of the one-House veto in these cases is confirmed by the character of the congressional action it supplants"). This principle should be extended to apply to actions undertaken by independent agencies and executive departments. There is no reason to limit application of this principle to evaluating congressional exercises of legislative power.

The Regulations are legislative in both character and effect in two ways. First, by its own terms, § 264(c)(1) equates the Regulations to legislation. The alleged authority of the Sec-

retary to promulgate regulations arose only after Congress failed to pass legislation governing standards with respect to the privacy of IIHI within 36 months of the enactment of HIPAA. Second, the Regulations had the purpose and effect of altering the rights, duties, and relations of persons, including patients, providers, health care clearinghouses, health plans, HHS, Office of Civil Rights and others, all outside of Congress. Section 264(c)(1)("Such regulations shall address at least the subjects described in subsection (b)").

Subsections "a" and "b" also demonstrate the legislative character and effect of the Regulations. Subsections "a" and "b" direct the Secretary to make legislative recommendations regarding privacy of IIHI. They set a limited agenda for the Secretary: to make recommendations for future legislation. The difficult policy choices regarding rights, procedures, and uses and disclosure of IIHI were left to Congress. Subsection "a" explicitly directed the Secretary to submit "detailed recommendations on standards with respect to the privacy of [IIHI]." Those recommendations were to be received by a Senate Committee and a House Committee. As used, the word "recommendations" contemplated future congressional action. In the context of § 264, "recommendations" were sought to enable Congress to propose and possibly enact future legislation. The subjects contained in § 264(b) are legislative in nature and include the rights an individual should have, § 264(b)(1), the procedures for exercising those rights, § 264(b)(2), and the determination of permitted "uses and disclosures", § 264(b)(3). If Congress had enacted the recommendations with respect to those rights, everyone in the United States would have been affected. Similarly, the Regulations affect everyone in the United States—people and parties outside Congress.

The language seeking recommendations from the Secretary set forth in Subsections "a", "b", and "d" suggests that Congress was writing on a blank slate. It needed to be better informed before legislating. Under Subsections "a", "b", and

"d", Congress explicitly sought recommendations from the Secretary regarding those standards because it had not yet made any policy determination or value judgment regarding the standards for privacy of IIHI when it enacted HIPAA. Marci Hamilton, *Representation and NonDelegation: Back to Basics*, 20 Cardozo L. Rev. 807, 820 (1999)("The legislature holds primary responsibility to make the national policy choices, and the President may not take on those choices"). Congress had not balanced the interests of various constituencies regarding that subject matter.[10] However, Congress had recognized that it needed further advice. Consequently, HHS rulemaking authority under §264(c)(1) was equated to legislation and *carved-out* from the remainder of §1173 rulemaking authority.[11]

B. Congress Defectively Delegated Authority to the Secretary

Congress may only delegate power it received from the People. This principle adds a fourth component to the three-pronged "intelligible principles" test. It is derived from the

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[10] Institutionally, Congress is better able to balance multiple viewpoints than a single agency or department. *See*, Hamilton, 20 Cardozo L.Rev. at 814 ("The legislative branch serves the people by filtering the factions in the society and distilling those laws that will best serve the nation . . . [P]ositions must be funneled through a large number of ports before becoming governing law . . . [Congress] is capable of reaching more nuanced compromises on national issues"). In contrast, when lawmaking is delegated to the President, there is only one port of entry, one viewpoint, albeit representing the entire nation. When lawmaking is delegated to an agency or executive department, the viewpoint is even narrower and without electoral accountability. *Id.* at 819-21. It is evident that Congress and not the Secretary should be the filter setting national policy regarding health privacy. The Secretary received over 60,000 comments regarding the Original and Modified Regulations, 67 Fed. Reg. at 53182-83.

[11] Section 1173 authorized the Secretary to issue uniform national standards regarding: transactions, unique health identifiers, code sets, security and electronic signatures. In conference, privacy of IIHI had been moved out of §1173. 65 Fed Reg. at 82469-70.

understanding that the federal government is one of enumerated powers and that a principal may not delegate authority it lacks.

1. *The 104th Congress Could Not Have Delegated Its Authority Beyond the End of Its Term*

Since our nation's first days, "[e]very law enacted by Congress must be based on one or more of its powers enumerated in the Constitution." *United States v. Morrison*, 529 U.S. 598, 607 (2000); *McCulloch v. Maryland*, 4 Wheat. (17 U.S.) 316, 405 (1819). Those powers are constrained by the Constitution's procedural requirements, *see e.g.*, U.S. CONST. art. I, § 7, cl.2, and substantive requirements, *see e.g.* U.S. CONST. art. I, § 9. Another constraint is provided by the temporal limit on the congressional franchise.

The President and members of the Senate and members of the House represent different geographic constituencies, have different modes of election, and have different requirements for holding office. U.S. CONST. art. I, §§ 2 & 3, U.S. CONST. art. II, § 1 and U.S. CONST. amend. XVII. The Constitution further diffuses power by limiting the terms of the President and members of the Senate and House and by making those terms of different lengths, *i.e.* they have different temporal mandates. Senators are elected for six years. U.S. CONST. art. I, § 3, cls. 1&2 and U.S. CONST. amend. XVII. The President is elected for four years. U.S. CONST. art. II, § 1, cl. 1. Members of the House of Representatives are elected for two years. U.S. CONST. art. I, §2, cl. 1. The authority of each Representative, each Senator and the President does not extend beyond the expiration of his or her term in office, respectively.[12] Any extension of authority beyond the end of those terms would unconstitutionally transfer from the "people" the power of the people to choose their own repre-

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[12] *See* Joseph Story, *Commentaries on the Constitution of the United States* (Carolina Academic Press) Book III § 263.

sentatives.[13] One commentator characterized the holding of elective offices as a "temporary lease" from the nation's citizens. Alan Morrison, *A Non-Power Looks at Separation of Powers*, 79 Geo. L.J. 281, 282 (1990). Expressed in real estate terms, the Constitution does not allow "holdovers".

When Congress "delegates" its power to "make law"[14], the delegation must occur before the congressional term ends. The reasoning is simple. A principal may delegate to its agent only the authority within its possession. A principal may not delegate authority that it does not have. Each House and Senate member loses all authority from his or her constituents at term-end. Consequently, the end of a congressional term ends **subsequent legislative actions** by that Congress. Similarly, the President has no authority to sign or veto legislation once his or her term expires. If Congress, as principal, cannot exercise its legislative power, then an agent of that Congress may not exercise that power.

Under §264(c)(1), the 104th Congress did not attempt to delegate its authority during the remaining four-plus months of its term or even during the 24 months of the 105th Congress. It was not until the eighth month of the 106th Congress, *i.e.* 36 months after the enactment of HIPAA, that the Secretary could issue the Regulations. However, the Regulations could never have been issued if Congress had enacted health privacy legislation during the intervening 36 months. Once the 105th Congress began, the 104th Congress had no power. Beginning in January 1997, the 104th Congress had

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[13] George Washington said: "The power under the Constitution will always be in the People. *It is entrusted* for certain defined purposes, *and for a certain limited period, to representatives of their own chusing*; and whenever it is executed contrary to their Interest . . . their Servants can, and undoubtedly will be [ ] recalled." *Thornton*, 514 U.S. at 814n.26 (emphasis added)(citations omitted).

[14] The power to "make law" stands in contrast to the power to "fill-in details" or otherwise "execute" legislation. *See, Loving v. United States*, 517 U.S. 748, 771 (1996) (Kennedy, J.).

no power to "make law" with respect to health privacy standards or anything else. Consequently, the agent of the 104th Congress, the Secretary, lacked that power as well.

2. *Congress Provided No Policy or Boundary to Limit the Secretary's Authority*

Under the "intelligible principles" test, a delegation is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Mistretta v. United States*, 488 U.S. 361, 372-373 (1989)(citation omitted). A delegation is always subject to the legislation that authorized it. *Chadha*, 462 U.S. at 953-54 n.16.

It has been suggested that delegation to administrative agencies leaves a gaping hole in the Constitution's balanced structure of checks and balances because agencies are prone to be arbitrary and unaccountable. "The nondelegation doctrine in this scenario is crucial to liberty, because it prohibits general lawmaking from occurring in a structure both capable of arbitrary action and removed from the national scrutiny to which both Congress and the President are exposed by the constitutional structure." Hamilton, 20 Cardozo L. Rev. at 821.

Section 264(c)(1) fails to meet two of the "intelligible principle" criteria. First, there is no clearly delineated general policy. Second, there is no boundary on the delegated authority.

Neither the general policy statement contained in the Preamble to HIPAA nor the policy statement articulated as § 261 of the Administrative Simplification provisions of HIPAA "clearly delineates" a general policy that is applicable to the privacy of IIHI.

The Preamble provides that HIPAA is:

> "[a]n Act to amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health

> care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes."

110 Stat. at 1936. None of these stated purposes refer to privacy of IIHI.

Section 261, contains a statement of the purpose of subtitle F of HIPAA. 110 Stat. at 2021 (not codified but *appears* at 42 U.S.C. § 1320d note). The language at the end of § 261 (*i.e.* "through the establishment of standards and requirements for the electronic transmission of certain health information") does not provide the Secretary with authority to issue standards with respect to the privacy of IIHI. A fair reading of § 261's language points to § 1173, which is entitled "STANDARDS TO ENABLE ELECTRONIC EXCHANGE". It does not point to § 264, which is entitled "RECOMMENDATIONS WITH RESPECT TO PRIVACY OF CERTAIN HEALTH INFORMATION." Section 264 directed the Secretary to make recommendations. It did not direct the Secretary to establish any standard with respect to privacy of IIHI upon enactment. The only authority to issue such standards was contingent authority if Congress failed to enact legislation. The policy and purpose with respect to privacy of IIHI were to be determined by later legislation. HIPAA contained no policy or purpose with respect to privacy of IIHI. *But see South Carolina Medical Association v. Thompson*, 327 F.3d 346, 351 (4th Cir.), *cert. denied*, 540 U.S. 981(2003) (finding a "general policy" of privacy).[15]

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[15] Section 264(c)(1) and the Regulations are inconsistent with a policy of privacy. They apply only to covered entities and do not apply to other individuals and entities that wrongfully obtain IIHI. Exec. Order No. 13181 *reprinted in* 42 U.S.C. §1320d-2 notes. Furthermore, the Regulations do not apply to all private medical information but only to IIHI that is within the scope of §1173. Section 264(c)(1). If privacy were truly the policy, the Secretary would not have been able to reduce confidential-

The phrase "shall address at least" is used both to list the subjects of legislative recommendations to be submitted by the Secretary and to list the subjects of rulemaking authority to be delegated if Congress failed to pass legislation by the statutory deadline. The use of that phrase removed all limits on the Secretary's authority. In *A.L.A. Schechter Poultry Corporation v. United States*, the Supreme Court struck down, as overly broad, a delegation that merely affected all industries. 295 U.S. 495 (1935). The delegation in §264(c)(1) is much broader. Its impact is not limited to the healthcare industry or even to all industries. It affects everyone. Its impact is pervasive.

Section 264(c)(1) contains no boundaries to determine whether the Secretary has exceeded the authority granted by Congress. *See Yakus v. United States*, 321 U.S. 414, 423-424 (1944); *Chadha*, 462 U.S. at 953. It specifies only a minimal set of subjects to be recommended to Congress and a minimal set of subjects to be included in future regulations if Congress did not enact such legislation by the deadline. Although the Secretary was required to "address at least" the three subjects specified in §264(b), there are no limits or constraints upon those subjects. Potentially, the Secretary could have addressed an infinite number of subjects[16] and had unbounded discretion with respect to each subject that he or she did address. In *Whitman v. American Trucking Associations, Inc.*, the Supreme Court said, "[t]he very choice of which portion of the power to exercise—that is to say, the prescription of the standard that Congress had omitted—would *itself* be an exercise of the forbidden legislative authority." 531 U.S. 457,

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ity from the Hippocratic standard practiced by physicians throughout our nation's history.

[16] The meaning of the words "at least" is unambiguous. In mathematical terms, those words mean "greater than or equal to". There is no upper limit. Under the Plain Meaning Rule, the Court must construe the words as written. *Connecticut National Bank v. Germain*, 503 U.S. 249, 253-54 (1992) (Thomas, J.).

473 (2001) (Scalia, J.). The Secretary has exercised such forbidden legislative authority.

C. The Constitution Does Not Give Congress Authority to Impair a Physician's Confidentiality Obligations

It is black letter law that "the powers of the legislature are defined and limited." *Marbury v. Madison*, 1 Cranch (5 U.S.) 137, 176 (1803) (Marshall,C.J.). *See also*, The Federalist, No. 45, at 292 (Madison) (Clinton Rossiter, ed. 1961) ("The powers delegated by the proposed Constitution to the federal government are few and defined").

According to the Constitution, the states are prohibited from changing or "impairing" contractual obligations. U.S. CONST. art. I, § 10, cl. 1 ("No State shall . . . pass any . . . Law impairing the Obligation of Contracts. . . ."). Here, no state law is at issue. Rather, federal law (*i.e.* §264(c)(1) and the Regulations) acts to impair confidentiality obligations from physicians to patients.[17] No power of Congress to impair a contractual obligation was enumerated in the Constitution other than the Bankruptcy Clause. U.S. CONST. art. I, § 8, cl. 4.

> While section 10 of Article I of the Constitution is directed to the states alone, we think it nevertheless states the policy of the founders of the Government on the question of impairing the obligation of contracts and that any Act of the national legislature that does impair the obligation of contracts is contrary to that policy and not

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[17] Typically, a contract is formed when a patient receives care from a physician. The patient promises to pay or have a third party pay. The physician promises to diagnose and treat the patient. The physician also promises to keep the confidences of his or her patients. Dr. Benjamin Rush, a signer of the Declaration of Independence said: "[t]he most important contract that can be made, is that which takes place between a sick man and his doctor. The subject is human life. . ." American College of Physicians, Medicine in Quotations Online *at* www.acponline.org/cgi-bin/medquotes.pl (citations omitted).

> within the powers delegated to the National Government, except in specific cases, such as bankruptcy.

Johnson v. U.S., 79 F.Supp. 208 (Ct. Cl. 1948).[18] The lack of congressional power to impair contractual obligations is also confirmed by the need to include a provision in the Fourteenth Amendment in order to extinguish debts and obligations incurred in aid of the confederacy. U.S. CONST. amend. XIV, § 4.

Without a constitutional amendment authorizing Congress to enact laws impairing the obligation of contracts, § 264(c)(1) and the Regulations may not impair a physician's obligation to keep a patient's confidences. This is as true today as it was 219 years ago.[19]

CONCLUSION

For the foregoing reasons, the Court should grant *certiorari* and ultimately declare § 264(c)(1) unconstitutional and the Regulations void.

Respectfully submitted,

DAVID P. FELSHER
Counsel of Record
488 Madison Avenue
New York, NY 10022
(212) 308-8505

June 14, 2006

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[18] The impairment of physicians' obligations may not be justified by nor derived from the Constitution's other provisions. *But see, Continental Illinois National Bank and Trust Company of Chicago v. Chicago, Rock Island & Pacific Railway Company*, 294 U.S. 648, 680-81 (1935).

[19] The Framers understood the importance of a physician's confidentiality obligation. In fact, one key Framer, Dr. Josiah Bartlett, was founder and first president of the New Hampshire Medical Society. As New Hampshire's representative to the Continental Congress, he cast the first vote for the Declaration of Independence. He also cast the first vote for the Articles of Confederation. With the help and influence of Dr. Bartlett during its ratification convention, New Hampshire became the ninth state to ratify the Constitution, triggering the formation of the United States under Article VII. U.S. CONST. art. VII. Signers of the Declaration: Biographical Sketches (Josiah Bartlett) *at* www.cr.nps.gov/history/online_books/declaration/bio3.htm.

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CITIZENS FOR HEALTH; AMERICAN ASSOCIATION FOR HEALTH FREEDOM; AMERICAN ASSOCIATION OF PRACTICING PSYCHIATRISTS; AMERICAN MENTAL HEALTH ALLIANCE-USA; AMERICAN PSYCHOANALYTIC ASSOCIATION; NATIONAL COALITION OF MENTAL HEALTH PROFESSIONALS AND CONSUMERS; NEW HAMPSHIRE CITIZENS FOR HEALTH FREEDOM; SALLY SCOFIELD; TED KOREN, DC; MICHAELE DUNLAP, PSY.D.; MORTON ZIVAN, PH.D.; CALIFORNIA CONSUMER HEALTHCARE COUNCIL; CONGRESS OF CALIFORNIA SENIORS; HEALTH ADMINISTRATION RESPONSIBILITY PROJECT; DANIEL S. SHRAGER; EUGENE B. MEYER; JANE DOE; JANIS CHESTER; DEBORAH PEEL,

Petitioners,

v.

MICHAEL O. LEAVITT, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

AMICUS CURIAE BRIEF OF THE PROGRAM IN PSYCHIATRY AND THE LAW OF THE BETH ISRAEL DEACONESS DEPARTMENT OF PSYCHIATRY, HARVARD MEDICAL SCHOOL IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

GARY ZALKIN
Counsel for Amicus Curiae
GARY ZALKIN, ESQ., LICSW, COUNSELOR AT LAW, PC
77 Franklin Street, Third Floor
Boston, Massachusetts 02110
617-422-0232

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
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IDENTITY OF THE *AMICUS CURIAE*, STATEMENT OF ITS INTEREST IN THE CASE, AND SOURCE OF ITS AUTHORITY TO FILE[1]

The Program in Psychiatry and the Law of the Beth Israel Deaconess Department of Psychiatry, Harvard Medical School (the "**Program**") was founded by psychiatrists Drs. Thomas Gutheil and Paul Applebaum in 1979 to serve as a training program for forensic psychiatrists. In 1982, co-founder Dr. Harold Bursztajn, a psychiatrist and medical decision analyst joined as a clinical ethicist.

The Program has become a nationally-recognized think tank, consultation service, and clinical research unit that addresses a variety of issues involving the intersection of medicine and law. It draws psychiatrists, psychologists, attorneys, research methodologists, policy analysts, writers, and students from across the country to conduct empirical research and analyze critical topics such as patient confidentiality and consent, the health care provider-patient relationship, and risk management.

Because a key focus of the Program is the study of patient confidentiality and its role in the quality of medical care, the Program has a strong interest in the regulations that gave rise to this lawsuit. It is convinced that those regulations, if upheld, would dramatically diminish medical confidentiality in this country, which in turn would have an immediate and deleterious impact on the

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[1] The parties have consented to the filing of this brief.

Counsel for a party did not author this brief in whole or in part. No person or entity, other than the *Amicus Curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

quality of patient care in a number of circumstances, particularly for mental health treatment.

The Program's concerns for confidentiality and ethics impel it to alert the Court to the danger of the regulations violating the Hippocratic principle of confidentiality and the Nuremberg Code's principle of consent.

INTRODUCTION

Psychotherapy is an indispensable tool of this nation's health care system. Approximately one in four American adults has received mental health treatment in the past two years.[2] The results are often dramatic and can transform an individual who cannot cope with the simplest day-to-day tasks into an effective and productive member of our society. Successful psychotherapeutic treatment requires an extraordinarily high degree of trust between the patient and the psychotherapist. The psychotherapist must often ask a patient to disclose facts, thoughts, feelings and desires that are so personal, so private and so psychologically threatening that the patient's defense mechanisms and shame often have kept the patient from discussing this material with anyone, sometimes for decades. The requisite level of trust is almost impossible to achieve if the patient has even the slightest concern that the content (and sometimes the very existence) of his or her communications with the therapist will be disclosed to others. Therefore, even a slight risk of disclosure can destroy trust, and without trust, society would quickly lose

[2] Harris Interactive poll, *Therapy in America 2004*; http://healthinfo.nch.org/healthyliving/mindbody/april05mentalhealth.htm.

the benefits of psychotherapy. This Court itself has stated that "the mere possibility of disclosure may impede development of the confidential relationship necessary for successful [psychotherapy] treatment." *Jaffee v. Redmond*, 518 U.S. 1, 10 (1996) (invoking the Federal Rules of Evidence to extend the psychotherapist/patient privilege to federal cases).

The Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") was enacted, among other reasons, to "simplify the administration of health insurance." Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub.L. 104-191), Aug. 21, 1996, 110 Stat. 1936, preamble. Previous regulations promulgated under HIPAA (the final "**Original Rule**") required medical providers to procure their patients' consent before disclosing confidential information in most circumstances.[3] In 2002, the Secretary of the United States Department of Health and Human Services (the "**Secretary**") amended the Original Rule to remove the requirement that patients grant their consent before providers disclose private medical information (the "**Amended Regulations**").[4] The Amended Regulations have established a broad regulatory regime under which intimate medical records are routinely transmitted and disclosed to other entities and providers without either the knowledge or consent of the patient. The result has been to create a tendency toward

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[3] Standards for Privacy of Individually Identifiable Health Information (45 C.F.R. § 164.506(a)), Dec. 28, 2000, 65 Fed. Reg., at 82,810.

[4] Standards for Privacy of Individually Identifiable Health Information (45 C.F.R. § 164.506(a), Aug. 14, 2002, 67 Fed. Reg. at 53,268.

an environment of disclosure that ranges far beyond anything originally anticipated under HIPAA. A consequent and predictable disincentive to seek services will harm many patients (in addition to the public health) who otherwise would have received effective mental health care.

By destroying patient/therapist confidentiality, the disclosure environment that has evolved from the failure of the Amended Regulations to require that providers obtain patient consent will harm many patients who would have otherwise sought and received effective mental health care. Equally importantly, the Amended Regulations also violate patients' constitutional right to privacy in their medical information as defined by this Court. *Whalen v. Roe*, 429 U.S. 589, 598-600 (1977) (stating cases involving "privacy" include interest in nondisclosure of private information and interest in making important decisions independently). See also, *Ferguson v. City of Charleston*, 532 U.S. 67 (2001) (holding hospital's unauthorized reporting of positive cocaine test was unreasonable search absent patient's consent).

In addition, removing patients' ability to give or withhold consent for their private medical information to be disclosed implicates principles of the Nuremberg Code, which begins,

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit,

> duress, over-reaching, or other ulterior form of constraint or coercion . . . "[5]

Although the Nuremberg Code was established after the horrors of the Holocaust when experiments were conducted on individuals who were stripped of all rights, its underlying principles apply to all "vulnerable patient-subjects who in their quest for relief from suffering may be readily inclined to place their trust in physicians, either in therapeutic or experimental settings."[6] To paraphrase the clinical ethicist Harold Bursztajn,

> It would trivialize both the Shoah and [the disclosure of private medical information without consent] to draw facile equivalences between the ethical horrors of the former and the ethical dilemmas of the latter. On the other hand, we should not turn a blind eye to the lessons history has taught, even if the circumstances of the teaching were very extreme."[7]

The Secretary has asserted that allowing providers to disclose private information without patients' consent is necessary for the "efficient delivery of healthcare." *Citizens for Health v. Thompson*, Civ. No. 03-2267, 2004 WL 765356, at 14 (E.D. Pa. Apr. 2, 2004). The Secretary's assertion is contrary to thousands of years of medical ethics, knowledge and practice. Although medical ethics,

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[5] http://ohsr.od.nih.gov/guidelines/nuremberg.html.

[6] Harold J. Bursztajn, M.D. & Archie Brodsky, B.A., *Captive Patients, Captive Doctors: Clinical Dilemmas and Interventions in Caring for Patients in Managed Health Care*, 21 General Hospital Psychiatry 239-48 (1999) (http://www.forensic-psych.com/articles/artCaptive.html. at *10) quoting Jay Katz, an ethicist and psychoanalyst.

[7] Id. at *10.

case law and statutes provide for disclosure without patient consent in narrowly-defined circumstances,[8] patient consent has traditionally been considered a key requirement for the provision of competent and efficient medical care since the Hippocratic oath in ancient Greece: "Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private."[9] In fact, the Original Rule stated that patients' control over their private medical information was an essential element of providing quality health care.[10] Despite the Secretary's apparent attempt to create a conflict between a patient's desire for medical privacy and the need for the efficient delivery of care, experience points in the opposite direction. Medical privacy does not detract from quality care; it enhances it. Moreover, there is no evidence that the consent requirement compromised the efficient delivery of care in any way during the era when consent was the ethical norm, through the period of the approval of the Original Rule. By effectively eliminating a consent requirement that is as old as the medical profession itself, the Secretary is, in effect, conducting a medical experiment on the American people, without their consent, without the approval of the medical ethics community and without any showing that such a brash and unprecedented move is justified. Even worse, once patient trust is lost, regaining it will require far more than

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[8] See, e.g., *Tarasoff v. Regents of Univ. of Cal.*, 17 Cal. 3d 425 (Cal. 1976) (concluding that confidentiality can be broken if there is a serious danger of violence to another).

[9] http://www.nlm.nih.gov/hmd/greek/greek_oath.html.

[10] 65 Fed. Reg. at 82,467.

changing a regulation back to its original form. The time to act by reaffirming the right to medical privacy is now – before a trust that has been carefully built over the millennia is destroyed by the deficiencies of HIPAA.

Because removing patients' control over their medical information will compromise medical care in general, and mental health treatment in particular, *Amicus Curiae* supports the Petition for Writ of Certiorari to enable this Court to review the lower court's decision in this important matter.

ARGUMENT

The Program in Psychiatry and the Law of the Beth Israel Deaconess Department of Psychiatry, Harvard Medical School, has broad expertise with the intersection of psychiatry and the law and has long recognized the importance of confidentiality for medical records. The Program's analysis and position is entirely consistent with principles of medical ethics accepted since the days of Hippocrates and, prior to the promulgation of the Amended Regulations, with established statutory and case law. The Program also believes that the regulation of medical care by HIPAA's regime of sanctions and regulatory permission constitutes governmental action subject to constitutional review.

I. THE AMENDED REGULATIONS CONSTITUTE STATE ACTION THAT IMPAIRS THE EFFECTIVE AND EFFICIENT DELIVERY OF HEALTH CARE

The Amended Regulations directs medical providers to notify their patients that HIPAA authorizes providers to disclose private patient medical records for treatment, payment and health care operations to a variety of entities without patient consent.[11] Such entities include two groups – covered entities (*e.g.*, health plans, providers, health maintenance organizations and healthcare clearinghouses) and their business associates. Covered entities have been estimated to number approximately 600,000. The number of business associates is much larger.

The Amended Regulations serves to deepen the divide between health care providers and the health plans that pay for treatment. It benefits health plans, which are not subject to professional ethical codes, by streamlining the payment process. This may increase efficiency for multi-state entities, which were previously challenged by multiple state law standards. However, these efficiencies may be illusory based, in part, on the costs of patients' withholding information from their medical providers when they know their private medical records will not be kept confidential. These purported efficiencies have not resulted in any noticeable reduction in health plan premiums to date.

On the other hand, the Amended Regulations creates a conflicting set of obligations for health care providers, who are still subject to professional standards regarding

[11] 45 C.F.R. § 164.520 (2002).

confidentiality and patient privacy while also encouraged to forego seeking patient consent by the state action of the HIPAA regulations.

Theoretically, at the time that the Amended Regulations were promulgated, providers could have decided not to change their policies and could have continued the traditional practice of requesting patient consent before they share private patient data. Governmental incentives, however, encourage the violation of these traditional practices. Indeed, both prior to and during the period in which the Original Rule was in effect, the overwhelming majority of providers routinely acquired consent without difficulty or complaint. Unfortunately, the interaction of the Amended Regulations' granting "regulatory permission" to covered entities through governmental license, and the imposition of possible civil and criminal penalty provisions made it significantly more difficult for a provider to retain its old policies. Any provider still adhering to its original consent requirement for the disclosure of private medical information would now have increased exposure to HIPAA's civil and criminal penalties for unauthorized disclosure, even if the lapse were unintentional.[12] Yet any provider that changes its policy, under governmental regulatory permission, to no longer promise consent is, therefore, no longer at risk for such penalties. Even the most cursory risk management analysis would identify a virtually irresistible incentive for changing policies to drop consent, even if such consent were ethically required. The new regulatory regime rewards providers for removing the consent requirement and offers

[12] 67 Fed. Reg. at 53,213; 42 U.S.C. § 1320d-5.

potential punishment for keeping it. Thus, the governmental actions of regulatory permission and penalties embedded in the Amended Regulations strongly discourage medical providers from requiring patient consent before disclosing private information. At the same time, providers are still subject to ethical codes that require consent, creating a compliance dilemma. With the stroke of a pen, the Secretary created a governmental reward system that transformed the medical landscape in America from one that respected medical privacy to one that repeatedly tells patients that they have no right to control intimate data about themselves.

A. Removing Confidentiality of Private Medical Information Will Harm The Effectiveness and Efficiency of Health Care Currently Provided

Confidentiality is a critical part of any form of medical treatment, but it is a particularly acute need for psychotherapy. If psychotherapists cannot assure their patients that confidential information will not be disclosed without their consent, there can be no successful treatment. Therapy often focuses on patients both sharing material within the therapeutic relationship about which they may feel great shame, and on confronting that material in order to help them change their behavior. Without trust in their psychotherapists' ability to keep such matters confidential, patients will be much less likely to disclose the most crucial information.[13] Medical providers will

[13] See CALIFORNIA HEALTHCARE FOUNDATION, NATIONAL CONSUMER HEALTH PRIVACY SURVEY 2005 http://www.chcf.org/topics/view.cfm?itemID=115694.

therefore be far less able to accurately diagnose or treat their patients.

Eliminating patients' ability to control their medical information will thus make the delivery of medical services, especially psychotherapeutic services, less efficient and less effective.[14] More sessions will be required to provide the same treatment, if it can be provided at all. This Court has already acknowledged the dilemma of trying to provide psychotherapy without a promise of confidentiality:

> Treatment by a physician for physical ailments can often proceed successfully on the basis of a physical examination, objective information supplied by the patient, and the results of diagnostic tests. Effective psychotherapy, by contrast, depends upon an atmosphere of confidence and trust in which the patient is willing to make a frank and complete disclosure of facts, emotions, memories, and fears. Because of the sensitive nature of the problems for which individuals consult psychotherapists, disclosure of confidential communications made during counseling sessions may cause embarrassment or disgrace. For this reason, the mere possibility of disclosure may impede development of the confidential relationship necessary for successful treatment. *Jaffee*, 518 U.S. at 10.

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[14] Richard Sobel, *Maintaining Informed Consent for Doctor-Patient Confidentiality: More Serious Failings in the HHS Medical Records Regulations*, 6 J. Biolaw & Bus. 2 (2003) (explaining how removing patient consent will lead to increased cost and inefficiency to the provision of medical care).

B. Removing Confidentiality of Private Medical Information Will Decrease the Likelihood that Individuals Who Require Health Care Will Seek or Receive Such Care

As noted above, without the promise of confidentiality, patients will be less likely to share personal information needed to receive competent medical care. Equally alarming, many potential patients will be deterred from starting psychotherapy when they know that their private medical information may be disclosed against their wishes. Ironically, under the regulatory scheme created by the Amended Regulations, each and every patient who is considering psychotherapy is first asked to sign a form that explicitly tells him or her that disclosure without asking for consent is now the norm under law. Yet this Court has noted, "The psychotherapist privilege serves the public interest by facilitating the provision of appropriate treatment for individuals suffering the effects of a mental or emotional problem. The mental health of our citizenry, no less than its physical health, is a public good of transcendent importance." *Jaffee*, 518 U.S. at 11.

Any action that discourages those who need psychotherapy from seeking help imposes personal, social and governmental costs that go far beyond those borne by the individual patient. Therapy is often used to treat individuals who would otherwise commit antisocial acts that harm others. These very individuals, whose private information is likely to be particularly stigmatizing, will be far less likely to pursue treatment when they are asked to sign a form that tells them that they have no right to prevent their private information from being disclosed to others. By not seeking treatment for their conditions, be it drug or alcohol addiction, kleptomania, pyromania, pathological gambling or other addictive behaviors, these

citizens will be more likely to continue their behavior, harming themselves, others and society in the process.

C. The "Psychotherapy Note" Exception Is Not Sufficient to Prevent the Serious Erosion of Confidentiality

The Amended Regulations contain a provision that affords some protection to psychotherapy notes.[15] This protection, however, is illusory. The Amended Regulations define psychotherapy notes as, "notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record."[16] The notes exception, however, is far too narrow because it excludes diagnoses, medication prescriptions, treatment plans, symptoms, prognoses and dates and frequencies of treatment. Therefore, the fact that a patient is receiving care for drug or alcohol addiction, kleptomania, pyromania, pathological gambling or other addictive behaviors, would not be protected. Knowing that one's diagnosis would not be protected may be enough to deter many people from receiving treatment. For others, knowing that they could not keep the mere fact that they are receiving psychotherapy private would be sufficient to deter them from seeking treatment.

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[15] 45 C.F.R. § 164.508 (2002).

[16] 45 C.F.R. § 164.501 (2002).

II. THE RIGHT TO, AND IMPORTANCE OF MEDICAL PRIVACY IS WELL RECOGNIZED IN MULTIPLE RELEVANT ARENAS

A. Constitutional Law Guarantees a Right to Privacy

This Court has recognized some form of a right to privacy for 115 years. In 1891 it concluded that "no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others . . . " *Union Pacific Railway Co. v. Botsford*, 141 U.S. 250, 251 (1891). In Justice Brandeis' *Olmstead* dissent, he declared that "[e]very unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation of the Fourth Amendment." *Olmstead v. U.S.*, 277 U.S. 438, 477 (1928) (Brandeis, J., dissenting).

More recently, this Court concluded in *Griswold v. Connecticut* that the right to privacy was to be found in the penumbras of the First, Fourth and Fifth Amendments. 381 U.S. 479, 484-85 (1965). By allowing the state not only to permit disclosures of private medical information without patient consent but, as discussed above, to encourage such disclosures, the lower court in this matter has disregarded decades of this Court's precedents respecting citizens' privacy.

B. State Law and Codes of Professional Ethics Recognize the Importance of Privacy for Psychotherapeutic Treatment

i. State Statutes

All fifty states, as well as the District of Columbia, have enacted statutes that protect medical information related to the psychotherapist/patient relationship. In addition many states have ratified the code of ethics of national associations of practitioners.[17]

ii. Professional Codes of Ethics

For centuries, medical ethics has required that physicians maintain confidentiality regarding their patients' medical information. As noted above, the Hippocratic Oath, still used in many medical schools, requires such confidentiality. More formally, the American Medical Association's Code of Medical Ethics, E-5.059, "Privacy in the Context of Health Care," includes language stating that,

> Physicians must seek to protect patient privacy in all of its forms, including (1) physical, which focuses on individuals and their personal spaces, (2) informational, which involves specific personal data, (3) decisional, which focuses on personal choices, and (4) associational, which refers to family or other intimate relations. Such respect for patient privacy is a fundamental expression of patient autonomy and is a

[17] See CAROLYN POLOWY, SOCIAL WORKERS AND CLINICAL NOTES, App. 4 (2001).

> prerequisite to building the trust that is at the core of the patient-physician relationship.

Similarly, the National Association of Social Workers Code of Ethics directs its members to "protect the confidentiality of all information obtained in the course of professional service, except for compelling professional reasons . . . " such as "when disclosure is necessary to prevent serious, foreseeable, and imminent harm to a client or other identifiable person." The code also admonishes social workers to "not disclose confidential information to third-party payers unless clients have authorized such disclosure"[18]

Finally, the American Psychoanalytic Association, Principles and Standards of Ethics for Psychoanalysts, IX, Social Responsibility states that "1. The psychoanalyst should make use of all legal, civil, and administrative means to safeguard patients' rights to confidentiality, to ensure the protection of patient treatment records from third party access, and to utilize any other ethical measures to ensure and maintain the privacy essential to the conduct of psychoanalytic treatment. . . ."[19]

The fact that, despite clear privacy statements in their respective ethics codes, mental health professionals routinely ask their patients to sign a HIPAA form indicating that the patients have very limited privacy rights shows just how powerful the federal action embodied by the Amended Regulations is.

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[18] http://www.naswdc.org/pubs/code/code.asp at 1.07 Privacy and Confidentiality (h).

[19] http://www.apsa.org/ethics0105.pdf, IX Social Responsibility.

As Justice Brandeis famously noted: "Our government is the potent, the omnipresent teacher. For good or for ill, it teaches the whole people by its example. Crime is contagious. If the government becomes a law-breaker, it breeds contempt for law, it invites every man to become a law unto himself; it invites anarchy." *Olmstead v. United States*, 277 U.S. 438, 485 (1928) (Brandeis, J., dissenting). Here, through state action by regulatory permission and criminal and civil sanctions, the government is inviting medical providers to violate their ethical norms and patients' ethical and constitutional rights.

C. The Federal Rules of Evidence Recognize the Importance of Privacy for Psychotherapeutic Treatment

This Court determined, in 1996, that the Federal Rules of Evidence enabled the psychotherapy privilege to apply to federal cases. *Jaffee v. Redmond*, 518 U.S. 1 (1996). Notably, in *Jaffee* this Court compared the psychotherapist/patient privilege to the attorney/client privilege in that both are "rooted in the imperative need for confidence and trust." *Jaffee*, 518 at 10, citing *Trammel v. U.S.*, 445 U.S. 40, 52 (1980). It makes little sense to hold psychotherapist patient data in such high esteem that triers of facts cannot hear it when making decisions that can have life-altering consequences, while simultaneously holding it in such low esteem that patients are told at the beginning of a professional relationship that even their explicit attempts to withhold consent may have no effect. The next logical step is to wait a few years and argue that the combined impact of millions of signed "I-have-no-consent-rights" statements will eliminate any reasonable expectations, not only at the federal level but at common

law as well. Analogizing the psychotherapist privilege to the attorney/client privilege, the position taken by the Secretary would be similar to this Court stating that all attorneys are allowed to tell their clients that there is no attorney/client privilege while at the same time permitting them to assert the very same privilege in court. Taking the analogy further, it would be extraordinarily unusual for a cabinet secretary to enact regulations disposing of the attorney/client privilege or, as in this case, limiting it into irrelevance.

CONCLUSION

Medical privacy as a constitutional right is under siege through state action. Because the Amended Regulations put so much pressure on providers to insist that patients acknowledge they have no consent rights, ordinary Americans are faced with an awful choice – give up your right to control health information about yourself or do not receive medical treatment. Even the fortunate few who might be able to insist on medical privacy (by eschewing health insurance and paying their medical bills out of pocket) will see their medical privacy rights erode as the decisions of the overwhelming majority of patients render the reasonable expectation of medical privacy a historical curiosity. Once privacy is lost, many people will not pursue treatment in order to protect their medical secrets. Many more may pursue treatment but will decline to disclose information critical to diagnosis and treatment. The reduced flow of information will increase health care costs and medical errors, and thus reduce the quality of care.

Enabling patients to trust health care providers enough to share their most personal thoughts is the result of the combined efforts of medical professionals for thousands of years. Unfortunately, the Amended Regulations is destroying that trust in the blink of an eye. The cost will be immeasurable, both in dollars and in lives. Given the stakes, we pray that this Court will grant the Petition for Writ of Certiorari and address an issue of state action affecting medical privacy that will shape all of our lives for years to come.

Respectfully submitted,

GARY ZALKIN
Counsel for Amicus Curiae
GARY ZALKIN, ESQ., LICSW, COUNSELOR AT LAW, PC
77 Franklin Street, Third Floor
Boston, Massachusetts 02110
617-422-0232